Responsible Person for Pharmaceutical Logistics 1.11

1

Regulations

2

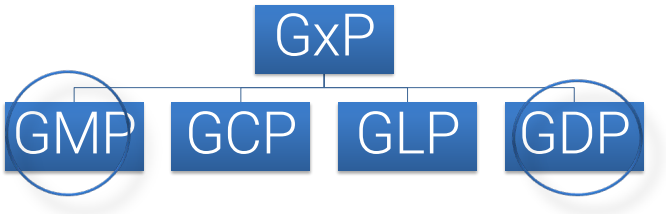
The Concept of GxP

GxP = Good (Pharmaceutical) Practice

- The purpose of the GxP quality guidelines is to ensure a product is safe and meets its intended use. GxP guides quality manufacture in regulated industries including food, drugs and medical devices.
- The most central aspects of GxP are:
  - Traceability
  - Accountability

3

The Concept of GxP



GMP: Manufacturing
GCP: Clinical
GLP: Lab
GDP: Good Distribution Practice
GSP – Good Storage Practice?

4

Global Regulators

5

Global Guidelines

Region	Regulations
EU	EU Guidelines on Good Distribution Practice of Medicinal Products for Human Use 2013/c 343/01- Adopted by the EU Sept 2013
PIC/S	Pharmaceutical Inspection Co-operation Scheme - Guide to Good Distribution Practice for Medicinal Products
Americas	DSCSA – Drug Supply Chain Security Act
Rest of world & Asia	WHO's "Good distribution practices for pharmaceutical products" and "Guide to storage practices for pharmaceuticals". Annex 5

6

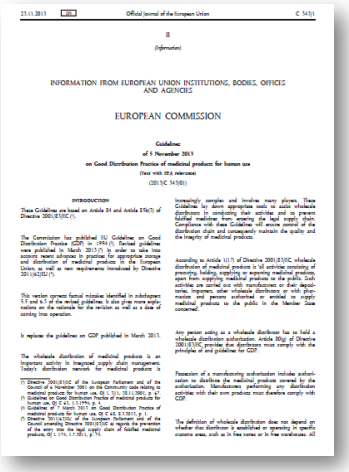
GDP = Good Distribution Practice

Good distribution practice (GDP) deals with the guidelines for the proper distribution of medicinal products for human use. GDP is a quality warranty system.

GDP regulates the division and movement of pharmaceutical products from the premises of the manufacturer of medicinal products, or another central point, to the end user thereof, or to an intermediate point by means of various transport methods, via various storage and/or health establishments.

7

EU Good Distribution Practice



INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

Revised Guidelines of 24 November 2013 on Good Distribution Practice of Medicinal Products for Human Use

(OJ C 343/1, 23.11.13)

8

PIC/S - Pharmaceutical Inspection Co-operation Scheme


PIC/S PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

PE 011-1
1 June 2014

PIC/S GUIDE TO GOOD DISTRIBUTION PRACTICE FOR MEDICINAL PRODUCTS

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web site: http://www.picscheme.org

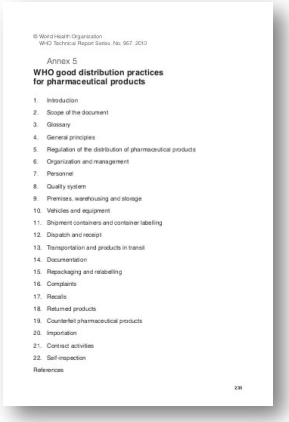
PE 011-1 Page 1 of 27 1 June 2014

Based on the EU Guidelines on GDP.

- Standards apply to medicines and similar products intended for human use. Guidelines also applicable for Investigational Medicinal Products
- Contains 9 Chapters

9

WHO Annex 5


© World Health Organization
WHO Technical Report Series, No. 957, 2010

Annex 5

WHO good distribution practices for pharmaceutical products

1. Introduction
2. Scope of the document
3. Glossary
4. General principles
5. Regulation of the distribution of pharmaceutical products
6. Organization and management
7. Personnel
8. Quality system
9. Premises, warehousing and storage
10. Vehicles and equipment
11. Shipment containers and container labelling
12. Dispatch and receipt
13. Transportation and products in transit
14. Documentation
15. Repackaging and relabelling
16. Complaints
17. Recalls
18. Returned products
19. Counterfeit pharmaceutical products
20. Importation
21. Contract activities
22. Self-inspection

References

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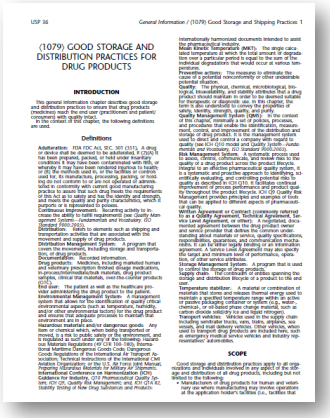
22 Chapters

"Every party active in the distribution chain has to comply with the applicable legislation and regulation"

"Every activity in the distribution of pharmaceutical products should be carried out according to the principles of GMP, GSP and GDP as applicable"

10

USP 1079



(1079) GOOD STORAGE AND DISTRIBUTION PRACTICES FOR DRUG PRODUCTS

INTRODUCTION

Definitions

Describes good storage and distribution practices that drug products reach the end user with quality intact

Applicable to all organisations and individuals involved in an aspect of storage and distribution

- Quality Management System
- Storage Management System
- Environmental Management System
- Transportation Management System
- Risk Management System

11

GDP Guidelines – Hot Topics

- Poor route validation
- Inappropriate QMS application and outputs
- Lack of understanding by the Responsible Person
- Unsuitable Risk Management use and application of control measures
- Risk Management not sensitive or sufficient.
- Customer Due Diligence

12

What is Medicinal Product?

The definition of a medicinal product in Article 1 of Directive 2001/83/EC was amended by Directive 2004/27/EC. The revised definition states that a medicinal product is:

(i) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

(ii) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

13

What is Medicinal Product?

A new provision has been added as Article 2(2) of Directive 2001/83/EC which now states that:

'In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a 'medicinal product' and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply'.

14

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15

What is Medicinal Product?

A drug is defined as:

- A substance recognized by an official pharmacopoeia or formulary.
- A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
- A substance (other than food) intended to affect the structure or any function of the body.
- A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device.
- Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process.)

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What is Medicinal Product?

17

Controlled Drugs

- Controlled Drugs (CD) are subject to additional legislation
- Need to be licenced to store and distribute these products by the local authority
- Requirements around being licenced premises, transport and people.

Examples: Amphetamines, Anabolic Steroids, Buprenorphine, Cannabis, Codeine, Morphine.

18

Cytotoxic

- Medicinal products used in the treatment of malignant disease
- Handling Requirements to be considered
- Low Risk as they are packaged
- Segregation Required
- Ensure packaged securely and identified by the Shipper

Examples: Methotrexate, Cyclophosphamide, Azathioprine.

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Radiopharmaceuticals

- Finished dose form containing a radioactive substance
- Used to diagnose, stage a disease, monitor treatment, or provide therapy. Low Risk as they are packaged
- Dangerous Goods regulations
- Transported safe and secure supply chain
- Protocol to address the occurrence of any theft.

Examples: Iodine-131, Fluorine-18, Gallium-67

20

Quality Management System Introduction

21

Quality Management

- Principle
  - Maintenance of a Quality System that describes
    - Responsibilities
    - Processes
    - Risk Management principles
  - Activities
    - Defined documented & reviewed
  - Processes
    - Justified and where relevant validated

22

Quality Management

What is a Quality Management System?

- A Quality Management System (QMS) is a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives
- It includes documents such as:
  - Standard Operation Procedures (SOPs)
  - Accompanying Documents (Logs, Forms, Charts etc.)
  - Organisation Policy
  - Training Records and Certificate
  - Equipment / Vehicle Certificates
  - Etc..

23

Quality Management

Why is a Quality Management System needed?

- A QMS helps coordinate and direct an organization's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis.

24

Quality Management

What are the benefits of having a QMS?

- Greater efficiency
- Better and Consistent control of major business processes
- Regulation of successful working practices
- Improved Compliance and Risk Management
- Increased customer satisfaction
- Improved participation of employees
- Better internal communication
- Greater consistency in the quality of products and services
- Reduction of costly errors
- Managing growth more effectively

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Quality Management

What is a GDP compliant Quality Management System?

- Defines all areas of the operation which can affect the safety and efficacy of medicinal products
- Controls by written, authorised procedures the storage and distribution of medicinal products
- It must ensure compliance to GDP all day, every day.
  - Auditable

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Quality Management

The system for managing quality should encompass the organisational structure, procedures, processes and resources, as well as activities necessary to ensure confidence that the product delivered is not adulterated during storage and/or transportation

- Appoint a Responsible Person
- All parts of the QMS are resourced adequately – Senior Management Responsibility
- Size and Complexity of the organisation should be considered – QMS design
- QMS should fully documented, and its effectiveness monitored
- Must have a change control system – This system should incorporate quality risk management principles

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Quality Management

The system should ensure that:

- medicinal products are procured, held, supplied or exported in a way that is compliant with the requirements of GDP;
- management responsibilities are clearly specified;
- products are delivered to the right recipients within a satisfactory time period;
- quality related activities are recorded at the time they are performed;
- deviations from established procedures are documented and investigated;
- appropriate corrective and preventive actions (CAPA) are taken to correct deviations and prevent them in lone with the principles of quality risk management

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Quality Management

Management of outsourced activities –

The Quality system should extend to the control and review of any outsourced activities related to the , procurement, holding, supply or export of medicinal products. These processes should incorporate quality risk management and include:

- Assessing the suitability and competence of the Contract Acceptor to carry out the activity. Check for the appropriate authorisation
- Defining the responsibilities and communication processes for quality related activities of the involved parties. For outsourced activities, this should be included in a written agreement between the contract giver and contract acceptor;
- Monitoring and reviewing of the performance of the contract acceptor, and the identification and implementation of any needed improvements on a regular basis

29

Quality Management

Management Review and Monitoring -

Senior management should have a formal process for reviewing the quality management system on a periodic basis. The review should include:

- Measurement of achievement of quality management system objectives;
- Assessment of performance indicators that can be used to monitor the effectiveness of processes within the quality management system, such as complaints, deviations, CAPA, changes to processes; feedback on outsourced activities; self assessment processes including risk assessments, and audits; external assessments such as regulatory inspections and findings and customer audits.
- Emerging regulations, guidance and quality issues that can impact the quality management system;

30

Quality Management

Management Review and Monitoring -

- Innovations that might enhance the quality management system;
- Changes in business environment and objectives.

The outcome of this management review of the quality management system should be timely and effectively communicated.

31

Quality Management

Quality Risk Management

Quality risk management is a systematic process for the assessment, control, communication and review of risks to the quality of medicinal products. It can be applied both proactively and retrospectively.

Quality risk management should ensure that the evaluation of the risk to quality is based on scientific knowledge, experience with the process and ultimately links to the protection of the patient. The level of effort, formality and documentation of the process should be commensurate with the level of risk.

Examples of the processes and applications of quality risk management can be found inter alia in the EU Guidelines to Good Manufacturing Practice or publications of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ('ICH').

32

Quality Management

Change Control

- Process to ensure changes are introduced in a controlled and coordinated manner
- Minimal disruptions and continued quality levels
- Cost effective utilization of resources

All changes relevant to processes and activities that directly or indirectly affect pharma operations/ services, must be recorded: equipment, facility, systems, supplier, process, SOP, forms, communications, reports, methodology, training, roles & responsibilities, job descriptions etc.

Steps in the process:

1. Submission of a documented change request -
2. Assessment of the request – Benefit to the organization, Risks
3. Implementation of the change
4. Review of the change

33

4 Main Components of a QMS

- Quality planning – Identifying objectives and relevant quality standards and deciding how to achieve them.
- Quality control – Inspecting and testing at appropriate points to identify any areas to improve in the product and/or service.
- Quality assurance – This component is process-oriented and focuses on issue prevention to ensure services and products meet specified requirements and standards when delivered.
- Quality improvement – Reviewing and evaluating your findings and improving areas that need changes. This improvement goes for the product and the processes, consistently looking at what is working and what isn't.

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Quality Metrics

- Mandatory regulatory requirements
- Customer-imposed requirements
- Contractual requirements
- Self-imposed requirements

✓ Quality requirements should provide a high degree of assurance that a packaging/transportation system qualified by the shipper is effective and consistent

✓ Quality parameters must address pharma risks

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How to begin writing a QMS?

- A QMS must be written with the 4 main components in mind (Quality Planning, Control, Assurance, Improvement) so that each procedure focuses on these components as well as the ALCOA+ principles.
- Each document should be written to meet to following:
  - To ensure the process meets the regulatory requirements
  - To ensure that the process is written clearly so that instructions are clear and concise to elevate potential risks
  - To ensure that the process is compliant
  - To ensure that the process is reviewed so that if an improvement has been identified the process could be updated / changed

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GDP Compliant Quality Management System

Source: asq.org

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Quality Risk Management

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Quality Risk Management

- A systematic process for the assessment communication and review of risks to the quality of medicinal products.
- Proactively and retrospectively applied
- Evaluate risk based on knowledge ,experience with the process and links to protection of the patient.
- Level of documentation should be commensurate with the level of risk

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Why Now?

- Products are becoming more complex and expensive
- Global Supply Chains are becoming more complex
- Supplying more high-risk locations, LATAM, Africa
- New legislation from Regulatory bodies
  - ✓ EU GDP and Falsified Medicines Directive (FMD)
  - ✓ Drug Supply Chain Security Act (DSCSA)
- Reduce costs

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Why Now?

- "Just in Time" or "Lean" Approaches
  - ✓ Outsourced Manufacturing
  - ✓ Contract Distribution
  - ✓ Multiple Subcontracting of logistical services
- Sophistication of Organized Criminal Cargo Theft/Counterfeiting Groups

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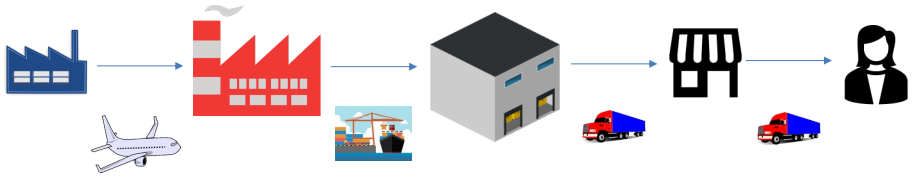
What could go wrong?



Physical Damage
Adulteration /Tampering/counterfeit
Exposure to unsuitable environmental conditions
Theft /Diversion
Compliance issues UK Bribery Act/US FCPA

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The Impact and Consequences of Loss

- Value of the product
- Cost to replace
- Clinical trial delay in obtaining approval
- Time delay to replace product to patient
- Company reputation
- Insurer – increased premiums
- Impact on society – deaths (no one's ever died as a result of a theft involving mobile phones)
- Backlash from authorities' Regulatory body of territory
- Loss of license
- Loss of Business

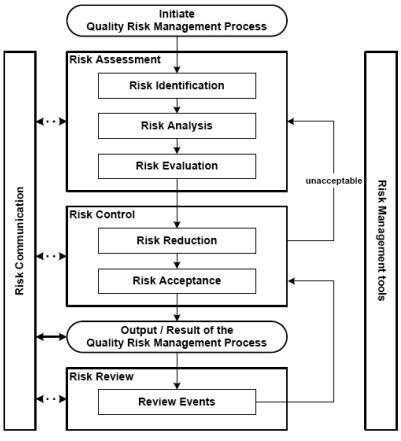
Preventing losses is your gain.....

43

Quality Risk Management

The evaluation of the risk to quality should be based on scientific knowledge and ultimately link to the protection of the patient.

ICH – Q9 International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use
Q9 Quality Risk Management



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Risk Based Approach

Managing Risk Key Steps:

- Define and document the Process
- Assess what could go wrong
- Likelihood or Probability it will go wrong
- Severity or consequence of the effect on the patient
- Detection –would you know if it went wrong
- Mitigate actions to eliminate or reduce the risk.
- Document and Approve Risk Assessment
- Monitor and Review Process

45

Risk Based Approach

Assess the Risk:

Establish Likeihood Rating

Likelihood	Meaning	Value
Rare	May occur only in exceptional circumstances (occurrence <1 n 1000)	1
Unlikely	could occur at some time (occurrence <1 in 100)	2
Possible	might occur at some time (occurrence <1 in 10)	3
Likely	Will probably occur in most circumstances (occurrence <1 in 4)	4
Almost Certain	Is expected to occur in most circumstances (occurrence <1 in 2)	5

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Risk Based Approach

Assess the Risk:

Establish Severity Rating

Severity	Meaning	Value
Insignificant	No impact on quality and/or efficacy of pharmaceutical product or internal quality system	1
Minor	Low-medium impact on quality and/or efficacy of pharmaceutical product or internal quality system	2
Moderate	High impact on quality and/or efficacy of pharmaceutical product or internal quality system	3
Major	Very high impact on quality and/or efficacy of pharmaceutical product or internal quality system	4
Catastrophic	Serious impact on organisations activities as a result of a critical competent authority observations, due to product safety and quality being compromised	5

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Risk Based Approach

Assess the Risk:

Establish Detection Rating

Detection	Meaning	Value
Very High	Control Method will almost certainly detect the existence of the problem	1
High	Control Method has a good chance of detecting the existence of a problem	2
Moderate	Control Method may detect the existence of the problem	3
Low	Control Method has a poor chance of detecting the existence of a problem	4
Detection is not Possible	Control method cannot or will not detect the existence of the problem	5

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Risk Based Approach

Assess the Risk:

Prioritisation Matrix

- Calculate the RPN – Risk Prioritisation Number
- Probability multiplied by Severity (PxSxD)

	Consequence				
Likelihood	Insignificant	Minor	Moderate	Major	Critical
Rare	LOW Accept the risk Routine management	LOW Accept the risk Routine management	LOW Accept the risk Routine management	MEDIUM Specific responsibility and treatment	HIGH Quarterly senior management review
Unlikely	LOW Accept the risk Routine management	LOW Accept the risk Routine management	MEDIUM Specific responsibility and treatment	MEDIUM Specific responsibility and treatment	HIGH Quarterly senior management review
Possible	LOW Accept the risk Routine management	MEDIUM Specific responsibility and treatment	MEDIUM Specific responsibility and treatment	HIGH Quartely senior management review	HIGH Quarterly senior management review
Likely	MEDIUM Specific responsibility and treatment	MEDIUM Specific responsibility and treatment	HIGH Quarterly senior management review	HIGH Quarterly senior management review	EXTREME Monthly senior management review
Almost certain	MEDIUM Specific responsibility and treatment	MEDIUM Specific responsibility and treatment	HIGH Quarterly senior management review	EXTREME Monthly senior management review	EXTREME Monthly senior management review

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Risk Based Approach

		Initial Risk Rating													
		1	2	3	4	5	6	8	9	10	12	15	16	20	25
Detectability	High (1)	1	2	3	4	5	6	8	9	10	12	15	16	20	25
	High (2)	2	4	6	8	10	12	16	18	20	24	30	32	40	50
	Medium (3)	3	6	9	12	15	18	24	27	30	36	45	48	60	75
	Low (4)	4	8	12	16	20	24	32	36	40	48	60	64	80	100
	Low (5)	5	10	15	20	25	30	40	45	50	60	75	80	100	125

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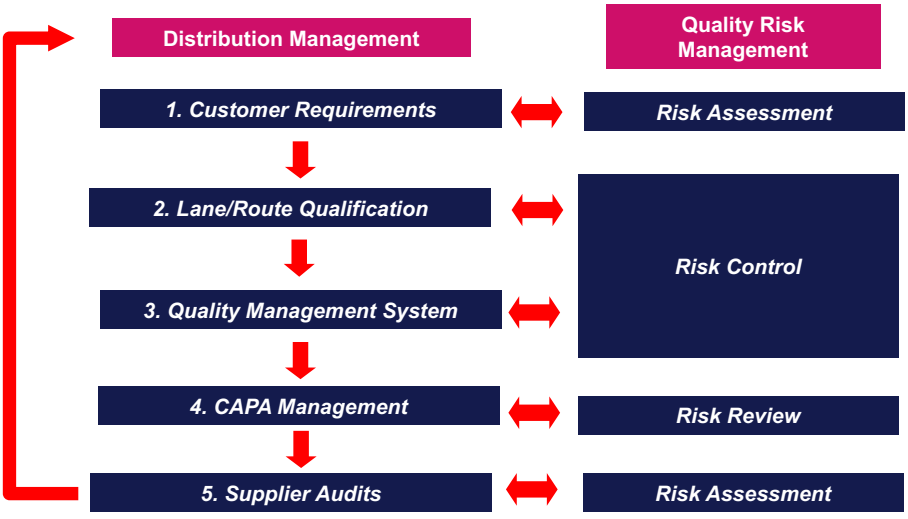
Risk Based Approach

Function or Process Step	Potential Causes	P	Potential Impact	S	Detection Mode	D	RPN= P × S × D
Briefly outline function, step or item being analyzed	What could go wrong?	How frequently is this likely to occur?	What is the impact on the output or the customer or internal requirements?	How severe is the effect (to the customer...)?	What are the existing controls that either prevent the failure from occurring or detect it?	How easy is it to detect, how efficient is the control measure in place?	Risk priority number

Detection part is optional

51

Risk based approach



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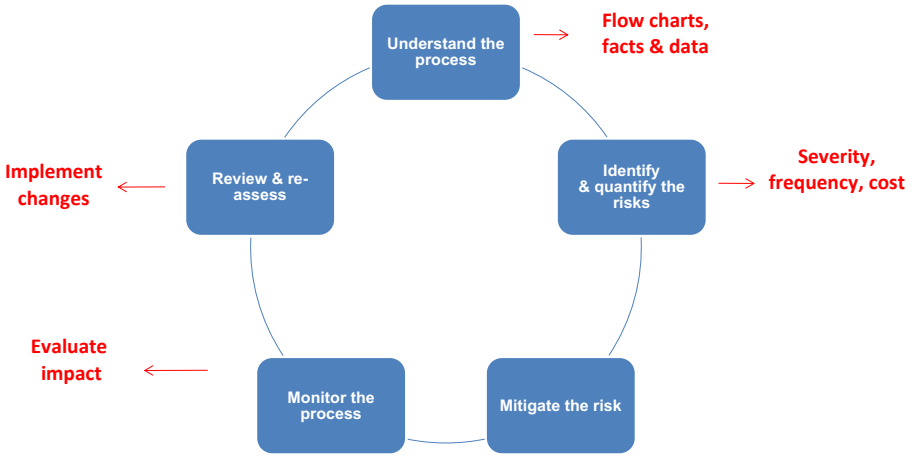
Risk Assessment Methodology



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Risk Analysis

Questions to ask

- What am I shipping?
- Are there any special conditions-temperature /security
- Where am I shipping it to?
- How am I shipping it?
- Who's shipping it and who's receiving it?
- What are the high-risk areas of the journey?
- What third parties are involved?
- What's the climate risk?

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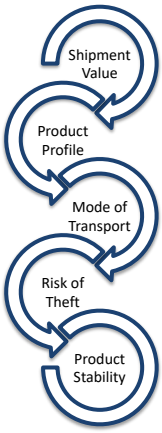
Risk Analysis Points to Consider



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Mitigating Actions Road Transport

Area	Requirements
Pre-business Audits	Undergo and pass audits regarding Security and Quality Contracts in place/SLA/QA/TA
Vehicles	Solid sided /sealing locks /panic alarm/GPS tracking /Geofencing/TCV/Temperature mapping of vehicles
Drivers	Double manned /Photo ID's/Full time/ Trained on Security /GDP have training matrix and records/background checked
Routes	Risked Assessed and documented
Warehouses	GDP compliant
SOP's	Quality Management System
Contingency Incident & Escalation Process	Secure parking policy Security Intelligence/Awareness

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Personnel

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Personnel

Correct distribution of medicinal products relies on people. There must be the sufficient competent personnel to carry out all the tasks.

- Individual responsibilities should be clearly understood by the staff and be recorded

Responsible person:

- Must be appointed
- Should meet the qualifications.
- Appropriate competence and experience – GDP
- Written job description
- Resources and responsibilities to fulfil their duties

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Personnel

Responsible person – Responsibilities

- Ensuring QMS is implemented and maintained
- Focus on the management of authorised activities and the accuracy of quality records
- Ensuring that initial and continuous training programmes are implemented and maintained
- Coordinating and promptly performing and recall operations for medicinal products
- Ensuring relevant customer complaints are dealt with effectively
- Ensuring suppliers and customers are approved
- Approving any subcontracting activities which may impact GDP
- Ensuring that self-inspections are performed at appropriate regular intervals following a prearranged programme and necessary corrective actions are put in place

59

Personnel

Responsible person – Responsibilities

- Keeping appropriate records of any delegated duties
- Deciding on the final disposition of returned, rejected, recalled or falsified products
- Approving any returns to saleable stock
- Ensuring that any additional requirements imposed on certain products by national law are adhered to

60

Personnel

Other personnel:

There must be the sufficient competent personnel to carry out all the tasks.

- Organisational Structure described in Organisational Chart
- Roles and responsibilities in key positions should have written job descriptions

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Personnel

Training:

All personnel involved in wholesale distribution activities should be qualified in GDP requirements by training and should have the appropriate competence and experience prior to commencing their tasks:

- Personnel to receive initial and continuing training relevant to their role
- Training to include aspects of product identification and avoidance of falsified medicines entering the supply chain
- Specific Products require specific training – Hazardous, Controlled Drugs, Radioactive Material
- Training Records – Periodic Assessments

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Personnel

Hygiene:

Appropriate procedures relating to personnel hygiene, relevant to the activities to be carried out, should be established and observed. Such procedures should cover health, hygiene and clothing.

- The storage of food, drink, smoking materials or medication for personal use in the storage areas should be prohibited.

63

Staff Training

How do you train your people effectively a step-by-step guide:

- **Understand GDP Guidelines:** Before you can train others, make sure you thoroughly understand the GDP guidelines yourself. GDP guidelines vary slightly depending on your industry, but they generally focus on maintaining the quality, safety, and efficacy of products throughout the distribution chain.
- **Identify Training Needs**: Assess the specific training needs of your team. Consider factors such as their current level of knowledge about GDP, any gaps in understanding, and the specific roles and responsibilities they have in the distribution process.
- **Develop Training Materials:** Create training materials that cover all relevant aspects of GDP.
- **Provide Hands-On Training**: Whenever possible, provide hands-on training experiences that allow your team to apply GDP principles in a practical setting.
- **Assess Learning:** Assess the effectiveness of your training program by soliciting feedback from participants and monitoring their performance over time.
- **Compliance Monitoring:** After training, establish a system for monitoring compliance with GDP guidelines.
- **Continuous Improvement:** Finally, view training as an ongoing process of continuous improvement. Keep abreast of changes in GDP regulations and industry best practices and update your training materials and approach accordingly.

64

Premises and Equipment

65

Premises and Equipment

Service Providers must have suitable and adequate premises, installations and equipment, so as to ensure proper conservation and distribution of the medicinal products.

Premises:

The premises should be designed or adapted to ensure that good storage conditions are maintained.

- Secure
- Structurally sound
- Sufficient capacity for storage and handling of medical products

66

Premises and Equipment

Premises:

- Contracts in place for outsourced activities
- Segregation of medical products – restricted access for trained personnel
- Segregated areas designated for the storage of products awaiting further decisions as to their fate.
- Appropriate degree of security should be applied in these areas to ensure that such items remain separate from saleable stock.
- Medicinal products not intended for the Union market should be kept in segregated areas.

67

Premises and Equipment

Premises:

- Requirement for storage conditions – Control MUST be in place to include temperature, humidity and light requirements.
- Attention paid to products with special handling requirements – Controlled Drugs – National Requirements
- Special handling for Hazardous and Radioactive Materials
- Specific requirements for receiving/dispatch bays – weather conditions
- Adequate separation between receipt/dispatch and storage areas
- Appropriate levels of site security and access control – monitored intruder alarms
- Storage facilities clean and free from dust and litter – Cleaning records should be in place

68

Premises and Equipment

Premises:

- Pest Control system
- Employee rest areas should be separate from storage areas

- Temperature and Environment Control
  - Suitable equipment and procedures in place to ensure control
  - Factors to consider – Temperature, humidity and cleanliness of premises
  - Storage areas should be temperature mapped under representative conditions and should take into account seasonal variations.
  - "Hot" and "Cold" areas

69

Premises and Equipment

Service Providers must have suitable and adequate premises, installations and equipment, so as to ensure proper conservation and distribution of the medicinal products.

Equipment:

All equipment used for storage and distribution of medicinal products should be designed, located and maintained to a standard which suits its intended purpose.

- Planned preventive maintenance should be in place for key equipment vital to the functionality of the operation
- Environmental Equipment (e.g. Temp Monitors) must be calibrated
- Calibration of equipment be must be traceable
- Appropriate Alarm systems must be in place - Temperature deviations

70

Premises and Equipment

Equipment:

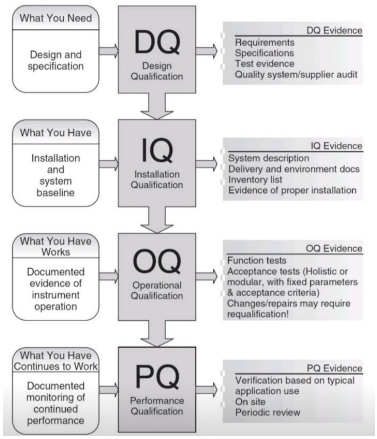
- Repair, maintenance and calibration of equipment must not compromise product integrity
- Demonstration of performance in the event of a power failure

- Computerised systems:

When software is used to collect, analyse, process of maintain data:

- Documentation must demonstrate the validity of the software

71



72

Qualification vs Validation

Qualification: To assure that a process is replicable under variable conditions

Validation: To describe how a system will perform under highly controlled conditions

73

URS and DQ

User Requirement Specification (URS) – The specification for equipment, facilities, utilities or systems should be defined in a URS and/or a functional specification.

Design Qualification (DQ) – The next element in the qualification of equipment, facilities, utilities, or systems is DQ where the compliance of the design should be demonstrated and documented. The requirements of the user requirements specification should be verified during the design qualification.

74

IQ/OQ/PQ

Installation Qualification (IQ) - Verification of the correct installation of components, instrumentation, equipment, pipe work and services against the engineering drawings and specifications; verification of the correct installation against pre-defined criteria

Operational Qualification (OQ) – OQ normally follows IQ but depending on the complexity of the equipment, it may be performed as a combined Installation/Operation Qualification (IOQ). OQ should include…… tests that have been developed from the knowledge of processes, systems and equipment to ensure the system is operating as designed

Performance Qualification (PQ) – Should include tests, using production materials, qualified substitutes or simulated product proven to have equivalent behavior under normal operating conditions with worst case batch sizes

75

Qualification & Validation - Vehicles

Installation Qualification (IQ) – Verification of installation (New Vehicles)

Vehicle description
- Make/Model/Chassis no.
- Evaporator make/model/Ser no.
- Monitoring system
- Air delivery systems (air chutes)
- Climatic curtains
- Bulk Heads
- Load limit lines

Evaporator configuration
- Set point
- High/Low & door alarms

Manuals/SOP's/WI's

Calibration status

76

Qualification & Validation - Vehicles

Operational Qualification (OQ) – Ensure system is operating as designed

Mapping at each required set pt e.g. +5/+20/-20
Pull Up/Pull Down Test
Power failure simulations
Min and Max load states
Static Mapping
- Can be mapped outside during Summer/Winter
- Can be mapped in environmental chambers
- Minimum of 24 hrs
- Report with hot/cold spots
- Acceptance Criteria (Allow for stress tests)
- Pass/Fail

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Qualification & Validation - Vehicles

Operational Qualification (OQ) – Ensure system is operating as designed

Mapping at each required set pt e.g. +5/+20/-20
Pull Up/Pull Down Test
Power failure simulations
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- Can be mapped outside during Summer/Winter
- Can be mapped in environmental chambers
- Minimum of 24 hrs
- Report with hot/cold spots
- Acceptance Criteria (Allow for stress tests)
- Pass/Fail

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Qualification & Validation - Vehicles

Performance Qualification (PQ) – Live tests under normal operating conditions

- Real or simulated loads
- Acceptance Criteria (Allow for stress tests)
- Furthest 'worst case' routes with longest journey times
- Summer & Winter Season considerations

79

Matrix Approach – Large Fleets

- Not feasible to qualify/map large fleets of vehicles
- Large fleets can be 'categorized' to condense the qualification requirements by focusing on Master vehicles (described as the Matrix approach)
- One sample (Master) vehicle is taken from each category and fully qualified (IQ/OQ/PQ)
- Live (PQ) data should still be obtained for vehicles not fully qualified
- Summer & Winter considerations

80

Matrix Approach – Large Fleets

Category Groups

- Trailer/vehicle manufacturer
- Age
- Size
- Control Unit Make/Model
- Air chute design
- Bulkhead type
- Single/Dual Chamber

81

Control and Monitoring of Storage/Transport Temperature

Outlined – Global Guidance

Why Control and Monitor Temperature?

Extremes of temperature can destroy Product.

82

Control and Monitoring of Storage Temperature

- Controlled Room Temperature Storage
- Controlled Room Temperature Distribution
- Cold Chain Storage
- Cold Chain Distribution

83

Control and Monitoring of Storage Temperature

- Controlled Room Temperature - Storage
  - Ensures product integrity through the shelf life
  - Room Temperature
  - Below +25°c and +30°c – Not Freezing

84

Control and Monitoring of Storage Temperature

Controlled Room Temperature - Storage

- Temperature Mapping
  - Study the temperature profile of the premises
  - Instrument the premises to study the areas of greatest risk – Temperature Map
  - Based on initial findings, commence monitoring on a regular basis

85

Control and Monitoring of Storage Temperature

- Controlled Room Temperature - Storage
  - Temperature Map Developed
  - Review temperature profiles of areas when outside temperatures are extreme – Hot and Cold
  - Review the temperature system controls
  - Ensure that you have a procedure in place that deals with excursion.

86

Control and Monitoring of Storage Temperature

Controlled Room Temperature - Distribution

- Risk assess the distribution system.
  - Conduct a detailed review of each stage of the supply chain process.
  - Extremes of temperature and establish control measures

87

Control and Monitoring of Storage Temperature

- Cold Chain Storage – 2°c to 8°c
  - Key Areas for review:
    - Type of Instrumentation
    - Validation Process
    - Recording of Data

88

Control and Monitoring of Storage Temperature

- Cold Chain Storage – +2°c to +8°c
  - Instrumentation:
    - Selection of recording equipment is critical
    - Data must be easily accessible – make it easy to read
    - Alarm system should be incorporated – High and Low
    - Calibration of equipment must be to a national standard

89

Control and Monitoring of Storage Temperature

- Cold Chain Storage – +2°c to +8°c
  - Validation:
    - Temperature Mapping for extreme temperature
    - Check on temperature variations during use
    - Validate back up system in case of power failure
    - Validate the Alarm system

90

Control and Monitoring of Storage Temperature

- Cold Chain Storage – +2°c to +8°c
  - Recording:
    - Check daily
    - Ensure a log to record the check
    - Ensure you have an SOP in place for high and low alarms
  - Ensure you regularly review records

91

Control and Monitoring of Storage Temperature

- Cold Chain Distribution – +2°c to +8°c
  - Selection of Packaging Solution is Key
  - It must be validated
  - Remember product type, journey times and temperatures
  - Must have temperature recording

92

Computerised Systems

- Before a computerised system is brought into use, it should be demonstrated, through appropriate validation or verification studies, that the system is capable of achieving the desired results accurately, consistently and reproducibly.
- A written, detailed description of the system should be available (including diagrams where appropriate). This should be kept upto-date. The document should describe principles, objectives, security measures, system scope and main features, how the computerised system is used and the way it interacts with other systems.

93

Computerised Systems

- Data should only be entered into the computerised system or amended by persons authorised to do so.
- Data should be secured by physical or electronic means and protected against accidental or unauthorised modifications. Stored data should be checked periodically for accessibility. Data should be protected by backing up at regular intervals. Back up data should be retained for the period stated in national legislation but at least five years at a separate and secure location.
- Procedures to be followed if the system fails or breaks down should be defined. This should include systems for the restoration of data.

94

Documentation

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Documentation

Good documentation constitutes an essential part of the quality management system. Clearly written documentation prevents errors from spoken communication and permits tracing of batch history. Instructions, procedures, and records should be free from errors and each employee should have access to such instructions and procedures concerning his or her activities at any time.

- Documentation – Written procedures, instructions, contracts, records and data. Paper or Electronic Form
- Documentation - Sufficiently Comprehensive with scope of activity
- Approved, signed and dated by authorised persons
- Changes should be dated and signed
- Retained for 5 years
- Documentation should be readily available

96

Documentation

- Any SOP issued to staff should not be the original document but one clearly marked “copy”
- There must be a version control system that withdraws “copies” when there are changes in procedures and replaces them with revisions
- Distribution must be known and documented
- Good Practice will have a formal review of SOPs on an annual basis
- This should be carried out in conjunction with the staff that do the job
- Reviews should be recorded, signed and dated.

97

Standard Operating Procedures

- A standard operating procedure (SOP) is a documented set of step-by-step instructions or guidelines designed to help individuals or organizations perform routine tasks or processes consistently and effectively.
- SOPs are commonly used in various fields such as healthcare, manufacturing, aviation, and many others where consistency, quality, and safety are crucial.
- They serve several purposes
  - Ensuring consistency
  - Facilitating Training
  - Improving Efficiency
  - Enhancing Safety
  - Meet Regulatory Requirements

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Standard Operating Procedures

SOPs in a GDP Compliant QMS

- Document Control
- Training
- Change Control
- Training
- Cleaning
- Pest Control
- Temperature Management
- Customer Complaints
- Outsourced Activities
- Self-Inspections
- Transportation
- Customer Authentication

99

What are the ALCOA+ Principles?

- The acronym 'ALCOA+' defines that data should be Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring and Available.

100

Attributable

- Data must be attributable means that all collected data must-have information on who collected the data, who acted, and when the action was performed.
- Every piece of data that is handled within an organisation needs to be attributable whether the data is physical or digital.

101

Example of Attributable Data

- Here you will see an example of a header section within a SOP, you will notice that the SOP has who has written the process (highlighted in red), this is how this SOP is attributable.

COMPANY
DELIVERY COMPANY

Procedure Title:	Procedure #001:	
Quality Risk Management	CMPY/GDP-001	
	Revision: 03	Page 1 of 2
	Written by: Joe Bloggs	Date of Creation: 01/07/2023 Date of Last Revision: 15/09/2023

102

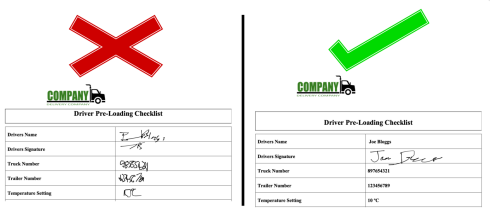
Legible

- Legibility means the collected data must be precise and understandable.
- This principle is more focused on paper-based data as digital data is typically legible, but you must ensure that every piece of data ,physical or digital, is precise and understandable.

103

Example of Legible Data

- Below you will see 2 example of data, one that has all elements clearly legible and understandable, the other with scribbled written making it illegible and difficult to read



104

Contemporaneous

- This means that the data must be recorded at the same time the action is performed.
- Whether this data is recorded automatically by a system (such as a sensor providing information to a system) or handwritten by an individual (a driver timestamping their vehicle checks), all data must be timestamped and recorded at the same time as the action is being performed and not after the fact.

105

Example of Contemporaneous Data

- Here you will see a temperature sensor report which has contemporaneous, you will notice that when there is a temperature excursion the system logs the exact time and duration of the event

Source	Alert UUID	Trigger Types	Minimum Activity Threshold	Incident Title	Start Time	End Time	Duration (hh:mm:ss)	Status	Severity	Source Type
162D23693	14033	Ambient temperature is outside range	1 minutes	'162D23693' ambient temperature has been outside range 16 -∞C to 24 -∞C for more than 1 minutes.	22/09/2023 13:54	22/09/2023 13:55	00:01:00	Automatically Resolved At 22 Sep 13:55	Unspecified	Temperature Sensor
Montracon Trailer - Sensor Back	14033	Ambient temperature is outside range	1 minutes	'Montracon Trailer - Sensor Back' ambient temperature has been outside range 16 -∞C to 24 -∞C for more than 1 minutes.	22/09/2023 12:33	22/09/2023 12:35	00:01:50	Automatically Resolved At 22 Sep 12:35	Unspecified	Temperature Sensor
Montracon Trailer - Sensor Back	14033	Ambient temperature is outside range	1 minutes	'Montracon Trailer - Sensor Back' ambient temperature has been outside range 16 -∞C to 24 -∞C for more than 1 minutes.	22/09/2023 12:29	22/09/2023 12:30	00:01:32	Automatically Resolved At 22 Sep 12:30	Unspecified	Temperature Sensor
Montracon Trailer - Sensor Back	14033	Ambient temperature is outside range	1 minutes	'Montracon Trailer - Sensor Back' ambient temperature has been outside range 16 -∞C to 24 -∞C for more than 1 minutes.	22/09/2023 12:08	22/09/2023 12:13	00:05:30	Automatically Resolved At 22 Sep 12:13	Unspecified	Temperature Sensor
151-D-36336 Back	14033	Ambient temperature is outside range	1 minutes	'151-D-36336 Back' ambient temperature has been outside range 16.5 -∞C to 24.5 -∞C for more than 1 minutes.	22/09/2023 08:09	22/09/2023 09:18	01:08:20	Automatically Resolved At 22 Sep 09:18	Unspecified	Temperature Sensor

106

Original

- Data that is to be retained must be original data
- Within an organisation documents should be retained as per national requirements, these documents must be the original documents, if there is copies of the original files in circulation then they should be marked as copies

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Example of Original Data

- Here you will see an example of how a report is watermarked as original so that it is easily identified, you will also see a report watermarked as copy

108

Accurate

- All data must be fully accurate meaning that it should be complete and free from any errors.
- In the case of manual data collection, this means having multiple individuals check the accuracy of data. In the case of electronic data collection, this means there must be redundant or duplicate systems in place to verify the accuracy.
- If changes are necessary, those changes must be documented in a way that makes it possible to refer back to the original information. Nothing should be removed, blocked out, or deleted.

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Complete

- All data that is recorded must be complete, nothing must be deleted or lost without reasons.
- There should be audit trails/ documentation to ensure that any changes to the data are captured with respect to the source of change as well as time.

110

Consistent

- This means that all data points must have a date and sometimes time attached to them, and it should be possible to create a chronology or sequence of events based on data.

111

Example of Accurate, Complete & Consistent Data

- In the next slide you will see a piece of data from a visitor log that is accurate ,complete & consistent.
- You will notice that every section within the log is filled, any changes made to the visitor log is detailed in the revision history section, and that the details filled into the visitor log are in chronological order.

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Example of Accurate ,Complete & Consistent Data

COMPANY
DELIVERY COMPANY

Form Title:	Form #:
Company Visitor Log	**CMPY-GDP Visitor Log**
	Revision: 02 / Page 1 of 1
	Written by: Jim Halpert / Date of Creation: 01/07/2023 / Date of Last Revision: 15/09/2023

Date	Visitor's Name	Reason for Visit	Phone Number	Time In	Time Out	Signature
10/05/2023	Dwight Schrute	Vehicle Maintenance	0851234567	09.01	15.29	DS
27/05/2023	Michael Scott	Delivery of Printer Paper	0877564312	09.30	09.45	MS
17/06/2023	Pam Beesly	Collection of Goods	0867654321	13.12	13.14	PdmB
27/06/2023	Michael Scott	Delivery of Printer Paper	0877564312	09.15	09.30	MS
01/08/2023	Dwight Schrute	Vehicle Maintenance	0851234567	08.57	15.45	DS

COMPANY
DELIVERY COMPANY

02/08/2023	Dwight Schrute	Vehicle Maintenance	0851234567	09.00	12.19	DS
27/08/2023	Michael Scott	Delivery of Printer Paper	0877564312	09.10	09.15	MS
17/09/2023	Pam Beesly	Collection of Goods	0867654321	16.45	17.02	PdmB
27/09/2023	Michael Scott	Delivery of Printer Paper	0877564312	09.30	09.42	MS

REVISION HISTORY

Rev	Change	Approved By	Job Title	Date Approved
00	Document creation	Jim Halpert	Responsible Person	01/07/2023
01	Added Telephone Number Column	Jim Halpert	Responsible Person	22/08/2023
02	Added Signature Column	Jim Halpert	Responsible Person	15/09/2023

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Enduring

- Enduring denotes the storage of data safely, long after the event has happened.
- This signifies the ability to store data in reliable places for a long duration (typically a 7-year retention period) - either as manual records or as a database.

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Available

- Data must be easily available whenever it may be needed.
- The key difference from the previous principle (Enduring) and this principle, is that this one emphasizes the ability to retrieve data easily at any point in time and not only about storing data.
- This key to this principle is the proper accounting of data in the form of indexes or labels.

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Operations

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Operations

Actions taken by the service provider should ensure the identity of the medicinal products is not lost and the wholesale distribution of medicinal products is performed according to the information on the outer packaging.

Areas of Focus:

- Qualification of Suppliers
- Qualification of Customers
- Receipt of Medicinal Product
- Storage
- Destruction of obsolete stock
- Picking
- Supply
- Export to third countries

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Qualification of Customer

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Qualification of Customer

EU GDP Guidelines

5.3. **Qualification of customers**

Wholesale distributors must ensure they supply medicinal products only to persons who are themselves in possession of a wholesale distribution authorisation or who are authorised or entitled to supply medicinal products to the public.

Checks and periodic rechecks may include: requesting copies of customer's authorisations according to national law, verifying status on an authority website, requesting evidence of qualifications or entitlement according to national legislation.

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Policy For Customer Qualification

6.0 HOW

There must be a documented process in place which outlines the steps to qualify and authenticate customers that they are entitled to receive our products. This must be completed prior to any goods being shipped to the customer.

This must include but not limited to;

- Obtaining a copy of the Wholesalers Dealer Authorisation (WDA) or the local equivalent.
- Obtaining copies of the customers' authorisation for possession and supply of controlled drugs or local equivalent.
- Verifying and documenting the status of the customer on an authority website.
- Carrying out due diligence checks regarding financial, corruption or any history of improper dealing.

Rechecking

Periodic checks should be carried especially if any suspicious behaviour or incidents are recorded or suspected.

Regular inspection of authority websites or approved lists should also be checked.

Issues

Any issues or concerns during authentication should be flagged ,documented and escalated to the local legal compliance team .

All due diligence documents and findings should be filed and be readily available for audit or investigation purposes.

7.0 MONITORING NARCOTIC TRENDS AND PATTERNS

Narcotic transactions (especially OxyContin Tablets) must be monitored for any unusual trends or patterns this could be;

- An unusual large quantity being ordered with no explanation
- An unusual quantity of high strength product being requested
- A sudden change of address for a delivery

8.0 REPORTING UNUSUAL TRENDS OR SUSPICIOUS ACTIVITY

Unusual quantities involving narcotic products must be investigated by contacting the customer to confirm the quantity requested.

120

Qualification of Customer

What processes do you have in place that reduces the risk of shipping counterfeit/falsified or diverted product?

How do you know your client is bona fide?

121

Qualification of Customer

EU GDP Guidelines

Qualification of customer

When entering into a new contract with a new customers the distributer should carry out "due diligence" checks in order to assess the suitability competence and reliability of the other party.

Attention should be paid to;

- Checking the financial status of the customer
- Is the contact managing the business relationship linked to the company they purport to represent?
- The reputation or reliability of the customer

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Due Diligence on Customer

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Qualification of Customer

Document and file findings

SECTION 1 – GENERAL INFORMATION	
Country	Ivory Coast
Supplier Company Name & Address (A)	Kent Pharmaceuticals Ltd Cambridge UK
Recipient Company Name & Address (B)	Nouvelle Pharmacie de la Sante Publique KM4 Boulevard de Marseille BP V5 ABIDJAN Côte d'Ivoire Ivory Coast Tel : (+225) 21 21 73 00 Fax : (+225) 21 21 57 70 Direction de la Logistique Pharmaceutique: 0022521217321 http://www.npsp.ci/
INCO Terms	DAP – customer is responsible for the Customs clearance
Warehouse Address	Nouvelle Pharmacie de la Sante Publique KM4 Boulevard de Marseille BP V5 ABIDJAN Côte d'Ivoire
Distributor	N/A
Customs Clearance Company	Customer's responsibility
Due Diligence	See attached
Security Audit	N/A
Security Questionnaire	N/A
Principal Contact(s)	Lukasz Witak

SECTION 2 – PRODUCT	
Products : MST CONTINUS Tablets 30mg & 10mg 60's	
Quantity: 30mg :120 packs 10mg 175 packs	
SECTION 3 – ROUTE	
Airline	Air France
Routes	London Paris Abidjan
Airport	London Heathrow Paris Charles De Galle Abidjan
Route Details (attach Google map)	N/A

Risk Assessment of Route(s)	Security audits have been carried out at Air France London Heathrow and Paris Charles De Galle. Both satisfactory		
SECTION 4 Due Diligence	Yes	No	Comments
• Narcotic Licence	X		See attached
• Security Assessment			
• Dow Jones Risk Assessment	X		See attached
• Anti-Bribery & Corruption Risk			
•			
•			
•			
SECTION 2 – Delivery			
POD received from airline attached			

Completed by: Tom Cochrane Sign:

Nom commercial	D.C.I	Forme et Quantité	Poids en produits anhydre par
MORPHINE SULFATE 30 MG BOITE DE 60	MORPHINE SULFATE	7 200 comprimés dosés chacun à 30 mg de MORPHINE, soit 120 boites de 60 comprimés.	Deux cent seize grammes (216 g)

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Qualification of Customer

FDA Drug Establishments Site Registration

https://www.fda.gov/drugs/drug-supply-chain-integrity/check-licensure-wholesale-drug-distributors-and-third-party-logistics-providers

https://dps.fda.gov/decrs

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Complaints, Returns, Suspected Falsified Medicinal Products and Medicinal Products recall

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Complaints, Returns, Suspected Falsified Medicinal Products and Medicinal Products recall.

All complaints returns, suspected falsified medicinal products and recalls must be recorded and handled carefully according to written procedures.

- Records must be available to the competent authority

Areas of Focus:

- Complaints – CAPA
- Returned Medicinal Products – Risk based process – Documented Evidence
- Falsified medicinal products – Must inform the competent authority
- Medicinal Product Recall – tested annually

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CAPA and Deviation Management

CAPA – Corrective Action, Preventative Action

CAPA is a regulatory concept that involves investigating, understanding, and correcting discrepancies while attempting to prevent their recurrence.

CAPA is a concept within good manufacturing practice (GMP), and numerous ISO business standards. It focuses on the systematic investigation of the root causes of identified problems or identified risks in an attempt to prevent their recurrence (for corrective action) or to prevent occurrence (for preventive action).

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CAPA and Deviation Management

CAPA system requires evaluation of an event according to the associated risk, categorizes it and acts accordingly in a timely manner, and verifies the effectiveness of the actions taken:

- A sequence of steps should be followed:
  - Event Detection – What has happened? Understand the Process. Retrospective or Current.
  - Decision Making Process / Deviation Categorization – Service Complaint? Product Complaint?
  - Deviation Treatment – High risk, Medium risk, Low risk. Think Patient Safety!
  - Root cause investigation – 5 Why?
  - Implement Corrective and Preventative Actions – Action, Owner and Closure Date

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CAPA and Deviation Management

Route Cause Investigation

- A thorough understanding of the entire situation is essential
- Without a root cause determination, you are only guessing
- And the PROBLEM will repeat itself

There are different Tools and Techniques we can use. One of the most effective is the 5 Why Principle.

The 5 Why Tool is a set of the five questions to reach the base of the problem but sometimes more than 5 questions are needed

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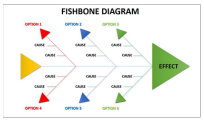
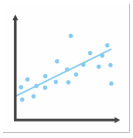
CAPA and Deviation Management

Other Tools and techniques for conducting root cause analysis:

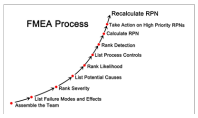
Pareto Chart



Fishbone Diagram



Scatter Plot



Failure Mode Effect Analysis

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CAPA and Deviation Management

DEVIATION REPORT

TO BE COMPLETED BY QUALITY SPECIALIST		
DR NUMBER: NCR-	DEVIATION OWNER:	PLANNED ☐ UNPLANNED ☐

1. IDENTIFICATION OF DEVIATION to be completed by notified person (Deviation)	
DATE OF INCIDENT:	
INCIDENT CLASSIFICATION:	Choose an item.
DATE REPORTED TO:	
REPORTED BY:	

CUSTOMER COMPLAINT REF:	CUSTOMER JOB/DN REF:	AWB REF:	JOB REF:	INCOTERMS:

Temp Requirement:			Thermal Packaging:		
+2°C to +8°C	+15°C to +25°C	Other:	Active – type:	Passive box – type:	Blankets – type:

CARRIER & PRODUCT:	ROUTING:	TOTAL #PLTS/CTNS:	#PLTS/CTNS AFFECTED:

2. BRIEF DESCRIPTION OF DEVIATION
N.B. IF DEVIATION RELATES TO REAL OR SUSPECTED FALSIFIED MEDICINE OR PHARMACEUTICAL PRODUCT ADVERSE EVENT THE CUSTOMER AND/OR COMPETENT AUTHORITY MUST BE INFORMED IMMEDIATELY

3. IMPACT OF DEVIATION

Rated As: High Impact ☐	Medium Impact ☐	Low Impact ☒

4. DETAILED DESCRIPTION OF DEVIATION AND INVESTIGATION CARRIED OUT

5. IMMEDIATE CORRECTIVE ACTIONS TO BE TAKEN

6. FURTHER CORRECTIVE ACTIONS REQUIRED to be completed by Deviation Owner		
ACTION	ACTION OWNER	TARGET ACTION CLOSURE DATE (dd/mmm/yy)

7. CONTRIBUTORY CAUSES AND ROOT CAUSE IDENTIFICATION to be completed by Deviation Owner

8. PREVENTATIVE ACTIONS to be completed by Deviation Owner		
ACTION	ACTION OWNER	TARGET ACTION CLOSURE DATE (dd/mmm/yy)

9. DOCUMENT REVIEW AND APPROVAL review/approval of depth/detail of investigation carried out and CAPA actions identified are appropriate to enable continuous improvement		
Function Head:	Responsible Person:	Complaint Owner:

Responsibilities:

- Lead Investigator (Customer Facing) – Manage and lead all aspects of the investigation
- Responsible Person – Oversee investigation, track CAPA Status, Review and Approve
- Impacted Departments – Provide expertise, insight and paths forward to assist in investigation

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CAPA and Deviation Management

Examples of where CAPA is used:

- Customer complaint – Temperature Excursion, Damaged Shipment, Delayed Shipment
- Risk assessment
- Internal audit, regulatory audit and Customer Audit – Nonadherence to regulation, Self Inspections
- Management review of KPI's – Trend Analysis, Management Review

"The purpose of the corrective and preventive action subsystem is to collect information, analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence." - FDA Food and Drug Administration

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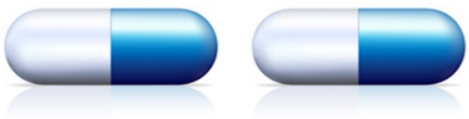
Falsified Medicines Directive

Can you tell which one of these medicines are fake?



Revised Directive of June 2011 to safeguard public health by protecting the pharmaceutical supply chain from infiltration by falsified (or counterfeit) medicines and introduces new rules to more rigorously regulate the Supply Chain.

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Falsified Medicines Directive

Main Provisions:

•To introduce a new safety features, which must appear on the outer packaging of designated medicines;

•To introduce more robust rules regarding the control on starting materials and inspection of producers of active substances and excipients contained in medicines;

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Falsified Medicines Directive

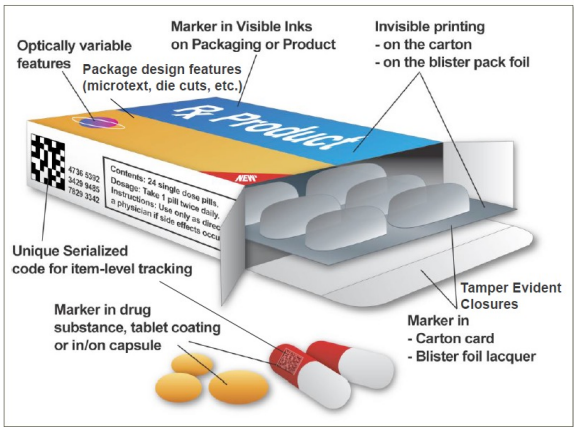
Main Provisions:

•To introduce more robust controls on the wholesale distribution of medicines, including introducing controls for the first time on entities involved in brokering medicines;

•To introduce a common, logo to identify legal online pharmacies and to establish a notification system for entities offering to supply medicines to the public over the internet.

136

Falsified Medicines Directive



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Counterfeit & Falsified Medicines

A counterfeit drug, defined as one that has been made by someone other than the genuine manufacturer of the item by either copying or imitating the drug without permission to do so.

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Counterfeit & Falsified Medicines

Falsified medicines are defined as:
Any medicinal product with a false representation of:
a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;
b) its source, including its manufacture, its country of manufacturing, its country of origin or its marketing authorisation holder; or
c) its history, including the records and documents relating to the distribution channels used

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Counterfeit & Falsified Medicines

- The annual global sales of counterfeit drugs are estimated to be between $200 billion and $432 billion
- Health authorities and Interpol are continually investigating and closing illegal operations.
- WHO estimates that 16% of counterfeit drugs contain the wrong ingredients.
- More than 30% of the counterfeit drugs that are available today don't contain any active ingredients whatsoever.

Source: Healthreserachfunding.org

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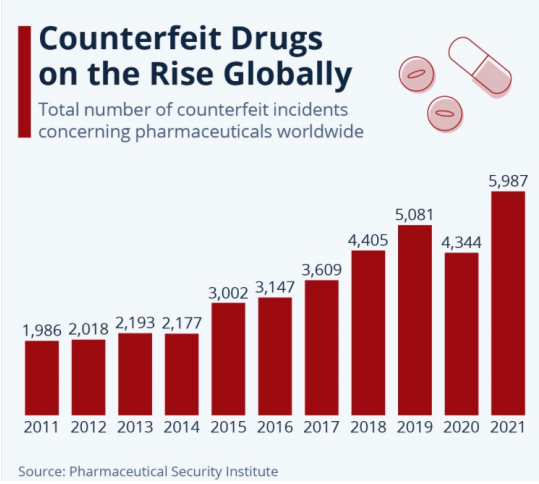
Counterfeit & Falsified Medicines



141

Counterfeit & Falsified Medicines

What must you do, as an RP, when you discover a Counterfeit or a Falsified Medicine:

- ✓ Quarantine/segregate the Medicinal Product and keep away from saleable stock.
- ✓ The License holder should be informed.
- ✓ The Competent Authority must be notified.
- ✓ If the product has been previously distributed to customers, a recall report must be generated and once product status is confirmed to be falsified or counterfeit, a recall will be instigated.

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FDA – Drug Supply Chain Security Act

U.S. Food and Drug Administration
Protecting and Promoting Public Health

DRUG SUPPLY CHAIN SECURITY ACT

4 Key Requirements

- Trading Partner authorization
- Product Tracing
- Verification
- Product Identification

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FDA – Drug Supply Chain Security Act

U.S. Food and Drug Administration
Protecting and Promoting Public Health

DRUG SUPPLY CHAIN SECURITY ACT

Trading Partner authorization

Any trading partner involved in the transfer of prescription drugs "where a change of ownership occurs" must be authorized such that they are appropriately registered or licensed to receive or transfer products.

For wholesale distributors and 3PLs, entities must have a valid state or federal licensure

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FDA – Drug Supply Chain Security Act

DRUG SUPPLY CHAIN SECURITY ACT

Product Tracing

Product tracing requirements involve receiving and providing product tracing data, including transaction history (TH), transaction information (TI), and the transaction statement (TS). Product tracing data must be provided with each transaction (i.e., at the sale of prescription drugs) and only prescription drugs accompanied by the required product tracing data should be accepted or received by trading partners.

145

FDA – Drug Supply Chain Security Act

DRUG SUPPLY CHAIN SECURITY ACT

Verification

Verification requirements under the DSCSA set forth practices for properly handling suspect and illegitimate products. DSCSA requirements with respect to suspect products include investigation and quarantine to determine if they are illegitimate.

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FDA – Drug Supply Chain Security Act

U.S. Food and Drug Administration
Protecting and Promoting Public Health

DRUG SUPPLY CHAIN SECURITY ACT

Product Identification

Product identifier information includes a National Drug Code (NDC), unique serial number, lot number, and expiration date and must be made available in both human- and machine-readable formats

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Outsourced Activities

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Outsourced Activities

Any activity covered in the GDP guide that is outsourced should be correctly defined, agreed and controlled in order to avoid misunderstanding, which could affect the integrity of the product.

Areas of Focus:

- Contract giver – Your customer! Assess your capability. Must provide you with all the information to carry out the contractual obligations
- Contractor acceptor – Adequate premises and equipment, procedures knowledge etc. to carry out the task. Must not outsource
- Falsified medicinal products – Must inform the competent authority
- Medicinal Product Recall – tested annually

149

Examples?

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Outsourcing

Code of Practice

Management of Outsourced Activities

The Quality System should include the control and review of any outsourced activities related to the transportation and temporary storage / cross-docking of pharma product.

Such GDP-related outsourced activities should be subject to Service Level Agreements (SLAs) which clearly define the responsibilities and communication processes for the quality-related activities of the parties involved.

151

Outsourcing

Code of Practice

Outsourced Transportation (Contractors)

Where transportation is performed by a contractor, a Service Level Agreement should be in place which ensures that all of the requirements of this CoP are adhered to.

It is the explicit responsibility of the Holder (specifically the RP) to ensure that all CoP requirements are continually maintained by their transportation contractor(s).

152

What is a Service Level Agreement (SLA)

- A negotiated, documented agreement between the customer and service provider
- Defines materials, service, quality specifications, and responsibilities
- A communication mechanism
- It can be either legally binding or an information agreement

153

What does a service level agreement do?

- It defines the minimum performance, operation or service levels
  - –Widely used in the pharma/biotech sector for outsourced manufacturing for better control & visibility
  - –Particularly useful in improving logistics chain interaction among stakeholders
  - –Creates the foundation of a partnership
  - –Targets performance criteria including training
  - –Includes processes that creates & communicates corrective / preventive actions
  - –An increasing regulatory expectation

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Creating an effective SLA

- The value of a Quality Agreement comes from the initial discussion and mutual understanding it brings
- Don't expect to be able to use the same agreement for all situations –adapt to suit specific needs
- Create regular day-to-day communication lines between stakeholders and use them.
- Provide feedback
- Be realistic about expectations, measure progress & share it

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Service Level Agreements

156

Auditing

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Purpose of Auditing

- Measure performance against prescribed specifications
- Determine areas of risk within the operation
- Ensure compliance to standards and regulatory requirements

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Purpose of Auditing

In the pharmaceutical industry, the primary purpose of an audit is to assess the effectiveness of an organisations' QMS system and its adherence to established standards, regulations and best practices. The following examples are where an audit is required which include:

- To look for compliance
- For-cause audit (following a deviation)
- Identifying risks
- Supplier audit and evaluation
- Following a change
- To promote improvements
- Regulatory Requirement

159

Definition

Audit – a scheduled and structured compliance level evaluation of implemented procedures in comparison to documented standards

160

Audit Terms

Compliance – implementation meets the documented specification or requirements

Non-compliance – implementation does not meet the documented specification or requirements

161

Audit Terms

Critical Finding - Indicates a serious compliance issue requiring immediate attention. Personnel injury or death may result through not correcting the non-conformity. Activity related to the non-conformity should be stopped until the problem has been fixed.

Major Finding – serious non-compliance that impacts of the quality or integrity of the product and requires action to prevent recurrence

Minor Finding (or Concern) – less serious non-compliance that must be monitored or remedied

Potential Improvements - Suggested improvement actions made by the auditors during the assessment. There are not linked to compliance but more for Continuous Improvement purpose

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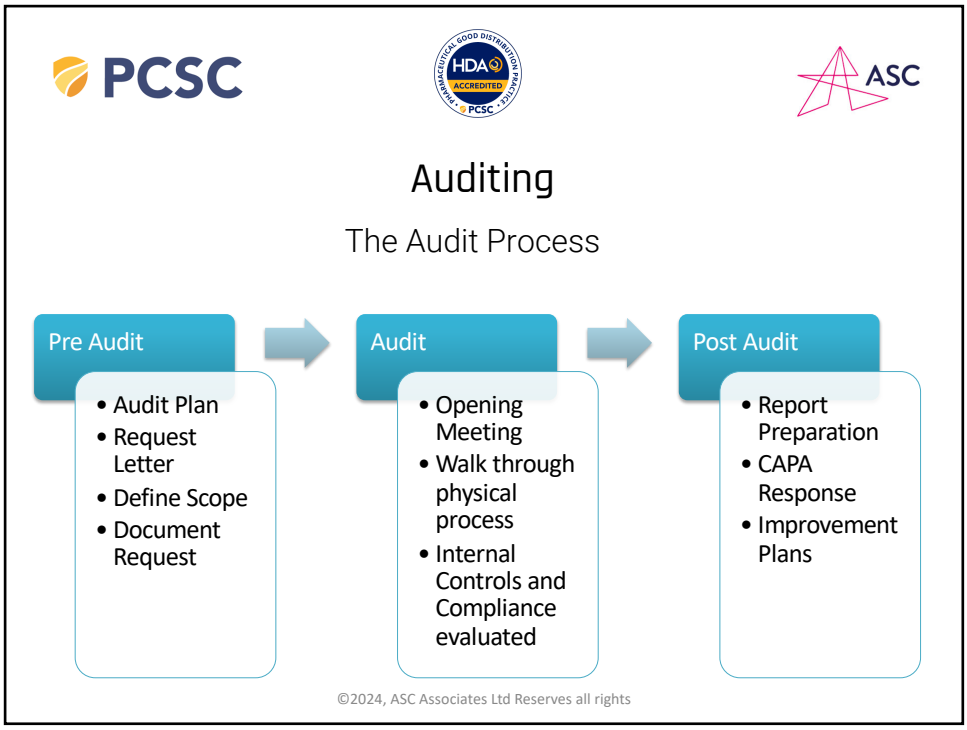
PCSC
HDA ACCREDITED
ASC
Auditing
The Audit Process
Pre Audit
• Audit Plan
• Request Letter
• Define Scope
• Document Request
Audit
• Opening Meeting
• Walk through physical process
• Internal Controls and Compliance evaluated
Post Audit
• Report Preparation
• CAPA Response
• Improvement Plans
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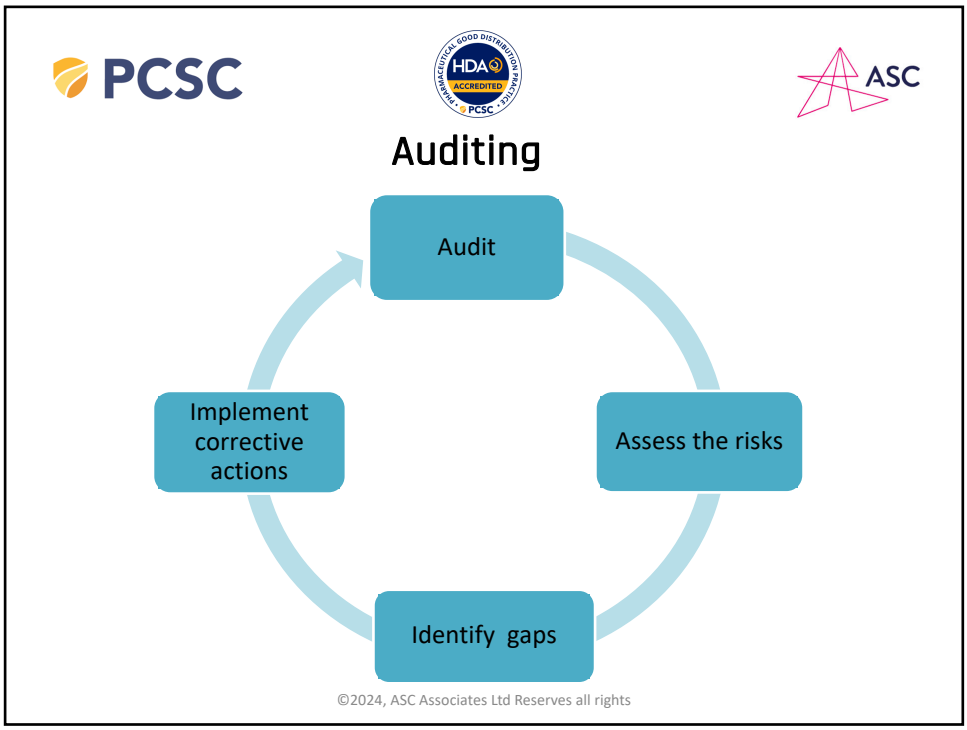
PCSC
HDA ACCREDITED
ASC
Auditing
Audit
Assess the risks
Identify gaps
Implement corrective actions
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Points to Consider

Prepare for the Audit – Auditor

- Prepare and Review documents
  - Determine the process and / or procedures
- Review records
- Need to understand the documented procedure in order to validate that it has been implemented

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Points to Consider

Prepare for the Audit – Auditee

- Build your own checklist for Audit Preparation
- Documents requested
- Availability of concerned people
- Logistical details such as meeting room, overhead projector, coffee break arrangements, lunch…
- Arrangements for visitors pass if needed

166

Points to Consider

Conducting Meeting

- Opening - Explain process, Confirm schedules and availabilities
- Daily - Report progress, Refine schedule
- Closing - Provide results, Show appreciation

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Points to Consider

Reporting Evidence

- Remain objective
- Do not make it personal
- Avoid being defensive
- Be clear and concise
- Anticipate questions

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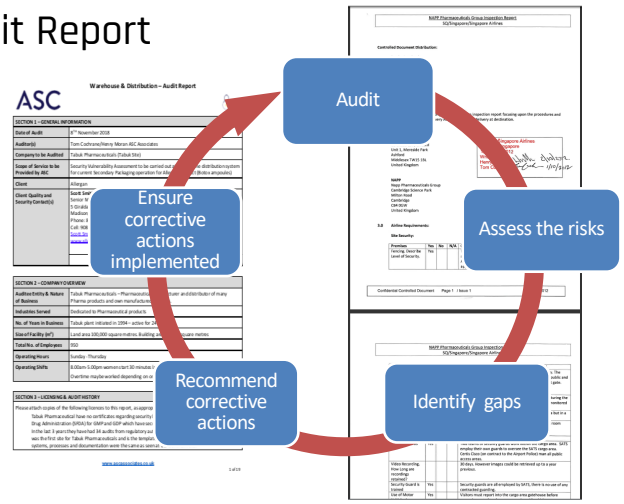
Audit Report



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Being Audited

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Types of Audits

- Regulatory Bodies
  - EU, US etc. grant and maintain license
- Your Pharma Customers
  - Pre business approval
  - Routine 3rd party audit
- Independent Bodies

171

What do auditors focus on?

- Standard Operating Procedures (SOP's)
- Quality Management System
- Temperature monitoring
- Facilities - freezers and refrigerators (validation)
- Product storage conditions
- Temperature control during transport
- Procedure for investigations and actions in the case of temperature excursion from the set parameters
- Staff training
- Supplier management

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Your Role - Auditee

- Personal appearance and “body language” (first impressions)
- Manage your nerves
  - relax, don’t panic
  - be prepared (understand your role)
  - feel comfortable (they like that)
  - be confident

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Your Role - Auditee

- When You’re Asked Questions
  - listen to the question (good answers)
  - answer only what is asked
  - use simple English
  - tell the truth
  - don’t be defensive or aggressive
  - if you don’t know, say so
  - be understood
  - the “silence gap” (be prepared and don’t be compelled)

174

Your Role - Auditee

- Never speak off the record (it's the company position - not your views)
- Be aware of your points of reference (paper or people)
- Be correct, complete, concise, clear and courteous
- Remember you are representing the company
- Take job satisfaction

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Your Role - Auditee

- Accompany auditor at all times
- Primary source of information (documents, questions, dealing with requests)
- Collating and retaining copies of documents
- Reporting back to management

176

Your Role - Principles

Some Golden Rules

1. Make sure you and your people know the relevant standards……and apply them!!
2. Do not interpret questions as a demand for action
3. Rapport…..based upon mutual trust an understanding (respect, honesty, each other's position)
4. Think…..before you speak
5. Do not comply first and complain after!

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Self Inspections

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Self Inspections

Self-inspections should be conducted in order to monitor the implementation and compliance with GDP principles and to propose necessary corrective measures.

A formal recorded process that aims to assess the degree of compliance with SOP's and GDP.

Might also be called:

- Auditing
- Reviews
- Quality Checks

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Self Inspections

- Should be conducted in an independent and detailed way.
- Conducted by designated staff or external bodies
- Audit of subcontracted activities should be part of the self inspection programme
- All self-inspections must be RECORDED.
- Report should contain all the observations made and circulated to senior management.

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Self Inspections

The self inspection process must be robust enough to identify any symptomatic and sporadic non-compliance with GDP. The self-inspection programme must take into consideration all applicable areas of GDP, the full scope of the QMS, a review of relevant records, personnel, premises, equipment, computerised systems and compliance with current legislation.

Particular attention to be paid to:

- The documented procedures and their suitability for the scope of activities
- Whether QMS outputs are raised contemporaneously and closed within the periods as set out
- Accuracy and availability of records
- Effectiveness of the QMS
- And changes in legislation and impact on activities

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Self Inspections

Proactive Approach:

- Enhanced Compliance and Risk Mitigation
- Improved Quality Control
- Increased Operational Efficiency
- Empowered and Engaged Employees
- Preparedness for External Audits
- Data for Continuous Improvement

A self-inspection program is a valuable tool for promoting quality, safety, efficiency, and continuous improvement. By taking a proactive stance, organizations can safeguard their reputation, avoid costly issues, and foster a culture focused on excellence.

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Self-Inspections

Area	Examples	Observations	Cause(s)	Corrective action	Timeline for completion	Corrective action performed?
Quality management	Are the deviations log and change control log to date? Have records been completed for deviations, change control and risk assessments? Have all issues been closed off? Has a management review been completed?					Yes ☐ No ☐
Personnel	Booster training provided to all personnel? All training records completed correctly? Have contracted drivers been trained?					Yes ☐ No ☐
Documentation	Have SOPs been reviewed? Any new SOPs issued in the year? - have relevant personnel been trained on these? - are index/distribution/revision forms up to date? Is the correct SOP version in use?					Yes ☐ No ☐

Area	Examples	Observations	Cause(s)	Corrective action	Timeline for completion	Corrective action performed?
	Have all records (cleaning, temperature etc) been completed correctly and reviewed where necessary? Is the information on the wholesaler's authorisation up to date?					
Premises / storage	Check the pick face for expired, damaged, incorrect stock Check pest control records - no. of visits up to date? Has temperature mapping or a risk assessment of the storage area been completed? Have temperature monitoring probes been calibrated? Check status of products in quarantine /reject areas. Are these recorded on the correct forms? Observe products being checked in and put away - in accordance with SOPs?					Yes ☐ No ☐
Approval of suppliers	Are there wholesaler's or manufacturer's authorisations on file for all suppliers? Are all GDP/GMP certificates on file? Are these up to date?					Yes ☐ No ☐
Order processing, picking and dispatch	Observe the picking of an order - is it in accordance with SOP? - are the records being signed and correct information recorded? - is order checked before dispatch? Check the cleanliness of the delivery vehicles.					Yes ☐ No ☐

Area	Examples	Observations	Cause(s)	Corrective action	Timeline for completion	Corrective action performed?
Transfer between branches	Was there transfer of medicinal products between branches? Were these recorded correctly (batch nos)?					Yes ☐ No ☐
Waste management	Check the status of products in the reject area - are these recorded in the Rejected Products Log? Can they be disposed of?					Yes ☐ No ☐
Return of medicinal products to inventory	Are goods checked before return to stock? Review Returns Assessment Forms - are they completed correctly? Observe processing of a returned medicinal product - in accordance with SOP? Check status of products in returns area.					Yes ☐ No ☐
Recall procedure	Has a mock recall been performed? Was it in accordance with SOP? Are the contact details up to date?					Yes ☐ No ☐
Customer complaints	Have there been any customer complaints? Were the records completed correctly? Was a reply received from the supplier? Was the complaint answered/closed out?					Yes ☐ No ☐
Falsified medicinal products	Were there any suspected falsified products received/identified? Were there any suspicious orders/requests? Were these notified to the HPRA?					Yes ☐ No ☐
Self-inspection	Has a self-inspection been performed in the last year? If not, why? Were all corrective actions identified implemented?					Yes ☐ No ☐

Area	Examples	Observations	Cause(s)	Corrective action	Timeline for completion	Corrective action performed?
	If training was required as a corrective action, was this performed and recorded? Was the self-inspection closed out?					
Outsourced activities	Is there an up-to-date list of outsourced activities? Has there been a recent assessment of the companies? Are all contracts up to date?					Yes ☐ No ☐
Transportation	Are all drivers trained in GDP? Have all transportation issues been investigated? Are vehicles clean and in good condition? Are medicines appropriately packed? Is all documentation included with each order?					Yes ☐ No ☐

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Transportation

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Transportation

Key Point to Note:

It is the responsibility of the wholesale distributor that, during the supply of medicinal products, the transport conditions are such as to maintain the quality of the product, to protect against breakage, adulteration and theft, and to ensure appropriate environmental conditions are maintained during transport. Adequate precautions should be taken to this effect.

Medicinal products should be transported in accordance with the storage conditions indicated on the packaging information.

185

Transportation

Key Point to Note:

Appropriate transport methods should be employed which may include transport by air, road , sea, rail or a combination of the above. Regardless of the chosen mode, it should be possible to demonstrate that the medicines have not been subjected to conditions during transportation that may compromise their quality. A risk-based approach should be utilised when planning transportation routes.

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Transportation

- Storage conditions must be maintained during transport
- If a deviation occurs during transportation, it must be reported to the distributor and recipient
- It is the responsibility of the service provider to ensure that vehicles and equipment used to distribute, store or handle medicinal products are suitable for their use.
- They must be appropriately equipped to prevent exposure of the products to conditions that could affect their quality and packaging integrity, and to prevent contamination of any kind.
- Delivery drivers must be trained in the relevant areas of GDP.

187

Transportation

- There should be procedures in place for the operation and maintenance of all vehicles and equipment involved in the distribution process, including cleaning and safety precautions.
- Attention should be paid to the fact that cleaning agents should not have an adverse effect on product quality.

188

Transportation

- Equipment used for temperature monitoring during transport should be maintained and calibrated at regular intervals – At least once a Year
- Dedicated vehicles and equipment should be used, where possible, when handling medicinal products. Where non-dedicated vehicles and equipment are used procedures should be in place to ensure that the quality of the medicinal product will not be compromised.
- Deliveries should be made directly to the address stated on the delivery note.
- If transportation is sub-contracted to a third-party then the contract should encompass the requirements contained within Outsourced Activities

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Transportation

- In the event that the transportation of medicinal products requires unloading and reloading e.g. at terminals and hubs, these premises should be audited and approved prior to deployment.

Areas for review:

Containers, packaging and labelling:

- Medicinal products should be transported in containers that have no adverse effect in product quality
- Selection of container and packaging should be based on the storage and transportation requirements of the medical products
- Labels should provide adequate information on the handling and storage requirements of the product.

190

Transportation

Areas for review:

Products requiring special conditions:

- In relation to deliveries containing medicinal products requiring special conditions such as narcotics or psychotropic substances, the service provider should maintain a safe and secure supply chain for these products in accordance with requirements laid down by the concerned competent authority
- Transportation of medicinal products comprising highly active and radioactive materials should be transported in safe, dedicated and secure containers and vehicles.

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Transportation

Areas for review:

Products requiring special conditions:

- Validated temperature-control systems (e.g. thermal packaging, temperature-controlled containers, and refrigerated vehicles) should be used to ensure correct transport conditions are maintained between the distributor and customer. Customers should be provided with a temperature data to demonstrate that products remained within the required temperature storage conditions during transit, if requested.

192

Transportation

Areas for review:

Products requiring special conditions:

- Temperature controlled vehicles: monitoring equipment used during transport should be maintained and calibrated at regular intervals or at a minimum of once a year.
- Remember Temperature Mapping!
- If cool-packs are used in insulated boxes, they need to be located such that the product does not come in direct contact with the cool-pack.
- Remember staff must be trained!

193

Transportation

Areas for review:

Products requiring special conditions:

- System in place for the re-use of cool packs…..
- Should be a procedure that covers unexpected occurrences such as vehicle breakdown or non-delivery.
- A procedure should also be in place for investigating and handling temperature excursions.

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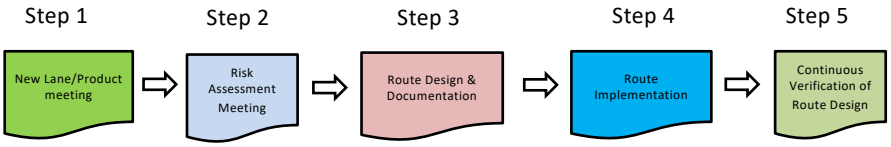
Process for New routes and Products



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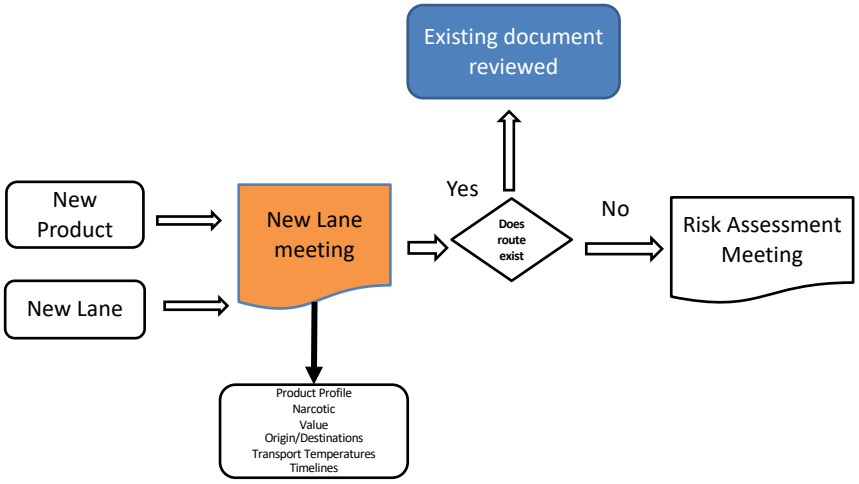
Process for New routes and Product



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Route Qualification

- It is a regulatory requirement that shippers demonstrate 'due diligence' when planning and executing their supply chain processes.
- This 'due diligence' must be extended to adequate scrutiny of the service and performance of their logistics partners, freight forwarders and carriers in undertaking the transportation of their products.
- This mandatory requirement is set out in the WHO technical report series No 961 – Transport Route Profiling and Qualification
- The process ensures all risks on critical control points within the transport route have been identified and mitigated and the whole process is proven to be effective in maintaining the required temperature range.

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Route Qualification

Effective route qualification and risk assessment consists of three key phases:

Pre-Assessment Planning → Risk Assessment Exercise → Post Assessment Evaluation

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Route Qualification

Pre- Assessment Planning

- Establish cargo & route details with shipper.
- Map out precise route details
- Identify key service partners and supplier stakeholders
- Assemble assessment team
- Establish RA process, documentation & data requirements

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Route Qualification

Risk Assessment Exercise

- Establish information flow and continuous monitoring.
- Assess shipment history noting any irregularities
- Consider shipper packaging and temp control solutions
- Map out critical Control points and responsibilities.
- Review environmental conditions and meteorological data.
- Conduct RA using preferred methodology

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Route Qualification

Post Assessment Evaluation

- Ensure data collection complete from all parties
- Complete RA analysis and conclusions on Risk priorities
- Assess risk mitigation measures and responsibilities
- Decide on corrective actions and instigate action plan
- Complete implementation of action plan and assess outcome
- Re-work RA and re-calculate risk priorities.

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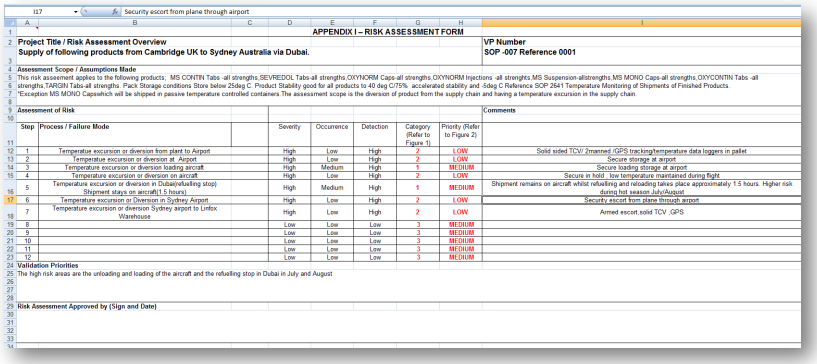
Risk Mitigation

Risk Assessment by Lane



APPENDIX I – RISK ASSESSMENT FORM

Project Title / Risk Assessment Overview	**VP Number**
Supply of following products from Cambridge UK to Sydney Australia via Dubai.	**SOP -007 Reference 0001**

Assessment Scope / Assumptions Made

This risk assesment applies to the following products; MS CONTIN Tabs -all strengths,SEVREDOL Tabs-all strengths,OXYNORM Caps-all strengths,OXYNORM Injections -all strengths,MS Suspension-allstrengths,MS MONO Caps-all strengths,OXYCONTIN Tabs -all strengths,TARGIN Tabs-all strengths Pack Storage conditions Store below 25deg C. Product Stability good for all products to 40 deg C/75% accelerated stability and -5deg C Reference SOP 2641 Temperature Monitoring of Shipments of Finished Products.
*Exception MS MONO Capswhich will be shipped in passive temperature controlled containers.The assessment scope is the diversion of product from the supply chain and having a temperature excursion in the supply chain.

Assessment of Risk

Step	Process / Failure Mode	Severity	Occurrence	Detection	Category (Refer to Figure 1)	Priority (Refer to Figure 2)	Comments
1	Temperatue excursion or diversion from plant to Airport	High	Low	High	2	LOW	Solid sided TCV/ 2manned /GPS tracking/temperature data loggers in pallet
2	Temperatue excursion or diversion at Airport	High	Low	High	2	LOW	Secure storage at airport
3	Temperature excursion or diversion loading aircraft	High	Medium	High	1	MEDIUM	Secure loading storage at airport
4	Temperature excursion or diversion on aircraft	High	Low	High	2	LOW	Secure in hold , low temperature maintained during flight
5	Temperature excursion or diversion in Dubai(refuelling stop) Shipment stays on aircraft(1.5 hours)	High	Medium	High	1	MEDIUM	Shipment remains on aircraft whilst refuelling and reloading takes place approximately 1.5 hours. Higher risk during hot season July/August
6	Temperature excursion or Diversion in Sydney Airport	High	Low	High	2	LOW	Security escort from plane through airport
7	Temperature excursion or diversion Sydney airport to Linfox Warehouse	High	Low	High	2	LOW	Armed escort,solid TCV ,GPS
8		Low	Low	Low	3	MEDIUM	
9		Low	Low	Low	3	MEDIUM	
10		Low	Low	Low	3	MEDIUM	
11		Low	Low	Low	3	MEDIUM	
12		Low	Low	Low	3	MEDIUM	

Validation Priorities

The high risk areas are the unloading and loading of the aircraft and the refuelling stop in Dubai in July and August

Risk Assessment Approved by (Sign and Date)

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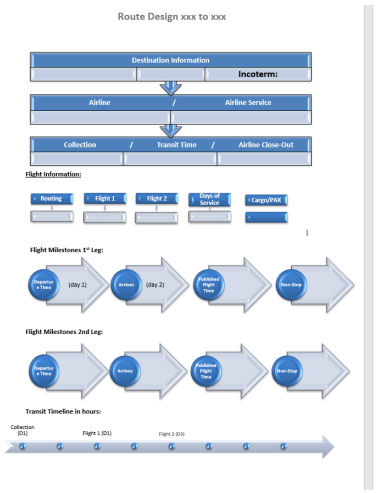
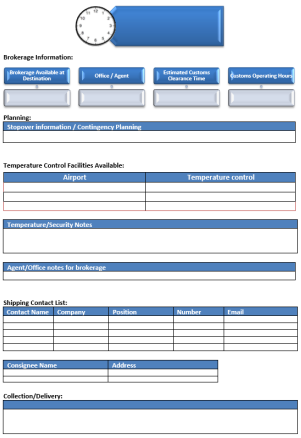
Route Design





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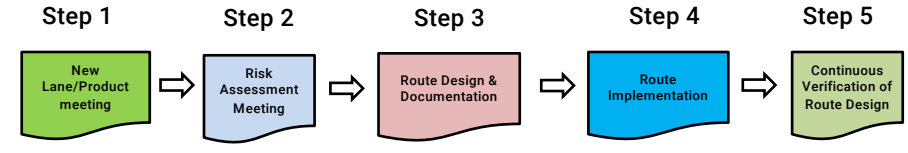
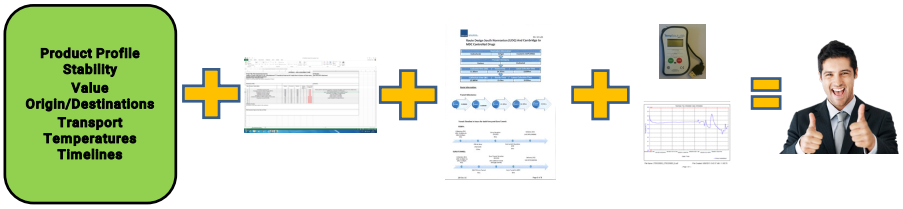
Process for new customers, routes and products





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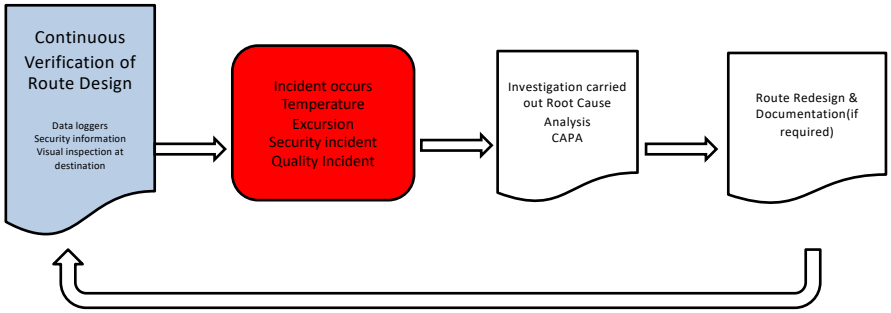
Process for new customers, routes and products



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Summary

- Understand the role of the Responsible Person
- Understand the importance of competent authorities
- Have a clear understanding of your key responsibilities and accountabilities with a clear focus on the legal and compliance aspects
- Be familiar with the GDP Guidelines
- Understand the importance of GDP

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Summary

- Understand Quality Systems
- Implementation of Quality Risk Management
- Understand how to establish and maintain bona fides for all your customers, and the compliant management of supply chains
- Appreciate the dangers and challenges posed by supply chain risks

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