



Auditing against the IPAC-RS Guideline

Using the Guideline as an Internal/External
Auditing tool

*Linda Nield, Quality Assurance Manager,
sanofi aventis, UK*

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Outline

- Auditing background
- Business benefits and regulatory expectations
- Standards and tools available
- Use of IPAC-RS GMP Guideline
- Summary
- Questions

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2



Audit definition

- An audit may be broadly defined as
'A systematic, independent and documented examination'



Why audit?

- Quality of medicinal products results from the sum of many activities
- End product testing alone is not sufficient to ensure product quality
 - An overall quality system is required that builds in the quality
 - This includes the entire supply chain
- Audits assess the effectiveness of the quality system and ensure the requirements of GMP are being met



Why audit?

- Well conducted audits serve both to meet regulatory requirements and to benefit the business
- Auditing is often the most appropriate way to gain the knowledge required to assess and approve suppliers.



Why apply GMP to supplied materials?

- Protect (assure) public health
- To ensure consistent standards of manufacture and control are applied
- For OINDP medicinal products, the components are a critical and integral part of the overall product.
 - à e.g., there is no MDI product without a functioning valve.
 - à The complexity of components, with multiple sub-components and N-2 and N-3 suppliers, increases the risk
 - Multiple suppliers = more locations/operations in which GMP and changes must be adequately controlled
 - à Component defects may not be evident until too late, e.g., until the defect causes a batch of finished OINDP to fail



Business benefits of auditing

- Audits can be a valuable business improvement tool
- A good audit looks at systems against current and anticipated future needs – from both a regulatory and business perspective.
- Audits are an important part of the partnership building process and can benefit both suppliers and customers
 - Process improvement
 - Ensure customer requirements are understood and met
 - Enable reduced activity – e.g. reduced quality control testing
 - Reduce the risk of costs associated with failure

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7



US and EU Regulatory Expectations for Auditing

- Limited detail on actual requirements
 - No explicit requirements within the USA Code of Federal Regulations
 - EU GMP Directives only have a clear requirement for self inspections (internal audits)
- However the need for audit is implicit to comply with other requirements
 - ‘The purchase of starting materials...should involve staff who have a..thorough knowledge of the suppliers’
 - ‘Starting materials should only be purchased from approved suppliers’

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8



Non Governmental Organization Regulatory Expectations for Auditing

- WHO GMP guide notes that:
 - ‘Before suppliers are approve, they should be evaluated.
 - The evaluation should take into account a supplier’s history and the nature of the materials to be supplied.
 - If an audit is required, it should determine the supplier’s ability to conform with GMP standards’

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9



Regulatory Expectations for Auditing: Take-Home Point

- Regardless of specific GMP guidance there is a clear expectation from regulatory authorities worldwide that audits are carried out – both internally and externally.

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10



Supplier view of OINDP industry?

- A view of the OINDP industry could be that
 - companies have inconsistent views on quality expectations
 - Don't understand suppliers and therefore have unrealistic expectations
 - Apply pharma standards where not necessary



Why?

A supplier could be audited by companies using any of the following...



- ISO 9000:2001
- 21 CFR 210 & 211
- EU GMP
- Company internal standards
- Others...
- PQG PS 9000:2001
- WHO GMP
- ISO 13485
- ISO 15378



Why?

- None of these Guidelines speaks specifically to OINDP
 - No guide for suppliers as to expectations of customers specific to OINDP components
 - Difficult to prepare for OINDP customer audits



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13



Use of Standards

- Standards or tools (or combination) are available for assessing appropriate quality standards and/or GMP standards in OINDP suppliers
- Standards can be used
 - Either through an audit of a supplier by a customer; or
 - For suppliers to perform internal audits in readiness for customer audit; or
 - For continuous improvement

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14



Use of Standards: Role of IPAC-RS GMP Guideline



- However...The IPAC-RS guideline is a harmonised quality standard
 - Incorporates PS 9000:2001, which includes ISO 9000 requirements (which many companies are familiar with)
 - Includes additional GMP considerations important for OINDP
 - Has been compared against ISO 15378 and is in alignment with it
- à Aim is to minimise the impact/number of differing customer requirements or auditing approaches

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15



Use of IPAC Guideline – Auditor (OINDP manufacturer)

- Clarity of requirements, as follows ISO 9001:2000 with specific GMP clauses
 - Aids audit preparation.
 - Lead auditor needs to be knowledgeable in GMP and specific requirements
 - May need to be accompanied by a technical expert familiar with specific requirements for OINDP
- The IPAC-RS guide gives a common basis against which to discuss appropriate standards with auditee at supplier

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16



Use of IPAC Guideline – Auditor (OINDP manufacturer)

- Able to assess all OINDP suppliers against a common standard
 - Initial evaluation and ongoing monitoring
- Increases ‘value added’ from audits if the basis is appropriate Quality and continuous improvement
 - Reduces the potential for frustration from both parties and helps to build partnership
 - Gives suppliers more guidance regarding your expectations



Use of IPAC Guideline – Auditor (OINDP manufacturer)

- Training and internal education
 - Helpful to get buy-in and support from QA leadership on use of Guideline
 - Critical to train your auditors on the use of the Guideline and specific concerns for OINDP



Next Steps: OINDP Manufacturers

- Please use the guide as often as possible with suppliers
 - as a basis for consistent auditing using a harmonised standard
 - to drive continuous improvement
 - to clarify requirements with suppliers
- Please make it available to all auditors of OINDP suppliers

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19



Use of IPAC Guideline – Auditee (OINDP Supplier/ N-1)

- Clarity as to the expectations from the customer
 - Gap analysis and audit preparation
 - Common language during audit and subsequent follow up
- Improve own business and better meet the needs of the customer – Proactive approach
 - Attracting new business & retaining current customers
 - Reduce frequency of audits
 - Demonstrate appropriate control

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20



Use of IPAC Guideline – Auditee (OINDP Supplier/ N-1)

- Use to build requirements into own quality systems, and use as a basis for internal audit and continuous improvement
 - Understand operations/ what is critical
 - Design and improve processes
 - Constantly seek better ways of doing business
- Tool for OINDP supplier to increase the understanding of requirements with n-2, n-3 suppliers and in preparation for auditing these suppliers
 - Context of increasing pharmaceutical standards



Next Steps: OINDP Suppliers (N-1)

- Please use the guide for internal audit/ self inspection
 - Gap analysis for process design and improvement
- Use in preparation for audits by OINDP customers
- Use for improving the communication and dialogue for quality improvement both internally, with your own suppliers (n-2) and with your customers.



Summary

- Pharmaceutical manufacturers need to audit for business benefit and as a regulatory requirement
- The IPAC-RS guide provides a harmonised standard for GMP for OINDP suppliers.
- The guide can be used for auditing suppliers to improve quality standards and help promote continuous improvement
- The guide can be used by OINDP suppliers for internal audit, audit preparation and to demonstrate commitment to meeting required quality standards

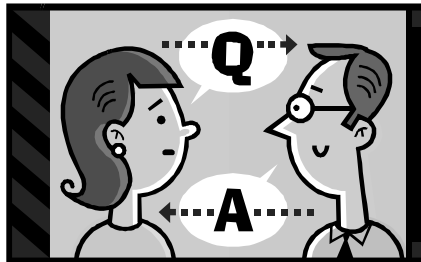
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23



Thank you for your attention

- Any Questions?



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24