

# Drug Product Approval in Europe

API Requirements

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# RESPONSIBILITIES

- The QP (qualified person) of the Manufacturing Authorisation Holder is responsible for the drug product in the European market.
- API GMP Declaration

# LEGAL REQUIREMENTS

- 1<sup>st</sup> Nov 2005 ICH Q7A Legal Requirement in EU
- The requirement is for audits to be carried by : MAHs or on their behalf.

# CONSEQUENCES

- EU Dosage Form Manufacturers
- API Manufacturers
- Increased costs & disruption for both Primary & Secondary Manufacturers

# STANDARDS

- Allocated Auditor Numbers & Time
- Report Content

# REGULATORY GUIDANCE

- QP
- EMEA Guidance
  - 3<sup>rd</sup> Party Audits
  - EU GMP Certificates
  - Remote Assessment

# REPHINE PLC

- PharmAssess is a unique 3<sup>rd</sup> party Auditing Service

*THANKYOU FOR YOUR ATTENTION*

*ANY QUESTIONS ?*