Supplier Quality Compliance - the changing landscape (an industry perspective)
Presentation Agenda

The changing landscape for Supplier Quality

- What has changed? Regulatory expectations
- Attributes of a successful supplier quality program
- Falsified Medicines Directive - an industry perspective
  - Supply Chain declarations
  - Supply Chain review
- Supplier Qualifications
Changing Regulatory Landscape

Early Years (1900-1961)
- Expectation on control of the finished drug product rather than incoming raw materials.
- Supplier Quality in infancy.

Developing GMP compliance (1961-1988)
- Pharmaceutical regulations require suppliers to be audited.
- GMP compliance introduced.

Maturing GMP Compliance (1989 -)
- Increased sophistication of the Supplier Management system.
- Development of the EU Guidelines and Regulations.
- Ongoing monitoring of suppliers.
Regulatory Changes

What has changed?

- Eudralex Volume 4 Chapter 7 Outsourced Activities
- Eudralex Volume 4 Chapter 5 Production
- EMA 33808 204 21 May 2014 QP declaration template
- Falsified Medicine Directive 2011-62
- Guidelines RA excipients OJEU 95.10
- EU GDP of API’s
- Good Distribution Practices Directive 2013
- MHRA data integrity issues
- USP1083 Good Distribution Practices
- Guidance for the template for the qualified person’s API’s
Successful Supplier Management Attributes

A robust system for the continual management of suppliers is necessary to assure the safety, identity, strength, quality, and purity of drug products.

- Know the guidelines and regulations
- Know your suppliers and the exact manufacturing site
- Know your supply chain
- Documents
  - Declarations (TSE/BSE, Residual Solvents)
  - GMP Evidence (ISO Certificates, Local GMP Accreditation)
  - Audit History – Regulatory inspections
  - Periodic Review – What is it telling you about the raw material
- Ongoing monitoring and evaluation of supplier
Know Your Supplier

Need to have good communication with your supplier.

- Do you know the exact site of manufacture?
- Do you have current contact details of the supplier?
- What are the API intermediates?
- Are they using outsourced laboratories?
- When was the last regulatory inspection?
- What was the outcome?
- Do you have a current QTA with the supplier?

How well do you know your supplier?
Changes to API supplier management at the PGS Melbourne Site

- Risk assessment of the API supplier
- Supply chain mapping (API plant to Melbourne Airport)
- Supply chain declarations
- Security of API during transport storage
- Temperature data loggers for all API shipments
- Security seal verification
- Stability data (long term and accelerated)
- Supply chain mapping Melbourne airport to facility
- Supply chain mapping facility to Distribution centre.
# API Supply Chain Declaration

## PART 1: API MANUFACTURER DETAILS

<table>
<thead>
<tr>
<th>API Manufacturer Name:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>API Manufacturing site location:</td>
<td></td>
</tr>
<tr>
<td>List all APIs supplied to Hospira Australia:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Do you import API into Europe?</th>
<th>YES/NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>If Yes, are you registered with the local Regulatory Authority for API importation? Please attach written confirmation (as Attachment 1).</td>
<td>YES/NO</td>
</tr>
<tr>
<td>Do you have a GMP Certificate from local Health Authority? Please attach a copy (as Attachment 2)</td>
<td>YES/NO</td>
</tr>
<tr>
<td>If No, please attach GMP certificate from another Regulatory body (as Attachment 3)</td>
<td></td>
</tr>
</tbody>
</table>

Please document the Supply Chain route of the API to Hospira Australia:

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Throughout the Supply Chain, identify and specify any risks to the API associated with theft, substitution, adulteration and spoilage.

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List actions to mitigate any risks to the API associated with theft, substitution, adulteration and spoilage.
## API Supply Chain Declaration

### PART 2: ARRIVAL AT AUSTRALIAN AIRPORT

<table>
<thead>
<tr>
<th>Part</th>
<th>Handling Agent</th>
<th>Unloaded by</th>
<th>Stored at</th>
<th>Custom cleared by</th>
<th>Transport/Service Agreement</th>
<th>YES/ NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arrival airport in Australia:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Handling Agent:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Transport/Service Agreement</td>
<td>YES/ NO</td>
</tr>
<tr>
<td>Unloaded by:</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Transport/Service Agreement</td>
<td>YES/ NO</td>
</tr>
</tbody>
</table>

### PART 4: API TRANSPORTED TO STORAGE WAREHOUSE PRIOR TO BEING DELIVERED TO HOSPIRA AUSTRALIA (MULGRAVE)

<table>
<thead>
<tr>
<th>Part</th>
<th>Transport from Australian Airport to Storage Warehouse</th>
<th>Storage Warehouse location</th>
<th>Transport from Storage Warehouse to Hospira Australia (Mulgrave)</th>
<th>Transport/Service Agreement</th>
<th>YES/ NO</th>
</tr>
</thead>
</table>


Supply Chain Review

- Are the storage and warehouses on your current approved supplier list?
- Have you performed an onsite audit?
- Do you have a QTA with the supplier?

Declaration needs to be completed every 2 years!

You need to provide assurance that the API has been transported within temperature requirements
Stability data (long term and accelerated)
Set up matrix and procedures (this can >12 months)
API Supplier Qualification

List GMP information: ________________________________________________________________

Does the manufacturer supply to other Hospira sites: □ Yes □ No     Who: ____________________________

Audit Questionnaire/Self Assessment Result: ___________________________ □ Satisfactory □ Unsatisfactory □ N/A

Latest Regulatory Authorities audit dates – Who/When _____________________________

Supplier Specification/CoA/CoC provided: ________________________________

Sample testing from three (3) individual supplier lots done and results: □ Satisfactory □ Unsatisfactory □ N/A

Audit date: ________________ Audit rating: □ Satisfactory □ Marginal □ Unsatisfactory □ N/A

CAPA plans and audit response(s): □ Acceptable □ Unacceptable □ N/A

TSE / BSE date: ______________________________________________________ □ N/A

Residual Solvents date: ________________________________________________ □ N/A

Aerobic Microbial Count (AMC) / Bacterial Endotoxin date: ______________________ □ N/A

Melamine / Asbestos (filters) declaration date: _____________________________ □ N/A

Quality Agreement established with manufacturer/supplier/distributor, date: ____________________________ □ N/A

Manufacturer has Approved Status in Global Approved Supplier List: □ Yes □ No

Supplier Risk Categorisation Assessment date: ___________________________ Result: □ High □ Medium □ Low

International API Supply Chain Declaration date: ___________________________ □ N/A

Local/Australian API Supply Chain Declaration: _____________________________ □ N/A

Stability data provided? □ Yes □ No □ N/A Comment: ______________________________

Conclusion:

This manufacturer meets requirements for site APPROVAL for supply of ___________________________ □ Yes □ No
QUESTIONS ?