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 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 ?

Falsified Medicines Directive

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	
API Manufacturer Name :	
API Manufacturing site location:	
List all APIs supplied to Hospira Australia:	
Do you import API into Europe?	YES/NO
If Yes, are you registered with the local Regulatory Authority for API importation? Please attach written confirmation (as Attachment 1).	YES/NO
Do you have a GMP Certificate from local Health Authority? Please attach a copy (as Attachment 2) If No, please attach GMP certificate from another Regulatory body (as Attachment 3)	YES/NO
Please document the Supply Chain route of the API to Hospira Australia:	
Throughout the Supply Chain, identify and specify any risks to the API associated with theft, substitution, adulteration and spoilage.	
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			
Arrival airport in Australia:			
Handling Agent:		Transport/Service Agreement	YES/ NO
Unloaded by:		Transport/Service Agreement	YES/ NO
Stored at:		Transport/Service Agreement	YES/ NO
Custom cleared by:		Transport/Service Agreement	YES/ NO

PART 4: API TRANSPORTED TO STORAGE WAREHOUSE PRIOR TO BEING DELIVERED TO HOSPIRA AUSTRALIA (MULGRAVE)			
Transport from Australian Airport to Storage Warehouse		Transport/Service Agreement	YES/ NO
Storage Warehouse location		Transport/Service Agreement	YES/ NO
Transport from Storage Warehouse to Hospira Australia (Mulgrave)		Transport/Service Agreement	YES/ NO

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

QUESTIONS ?