GLOBAL SUPPLY
Pharmaceutical Manufacturing Operations

D1.T1.3.2 – Changes in Regulations

Addressing the gap, some practical tips

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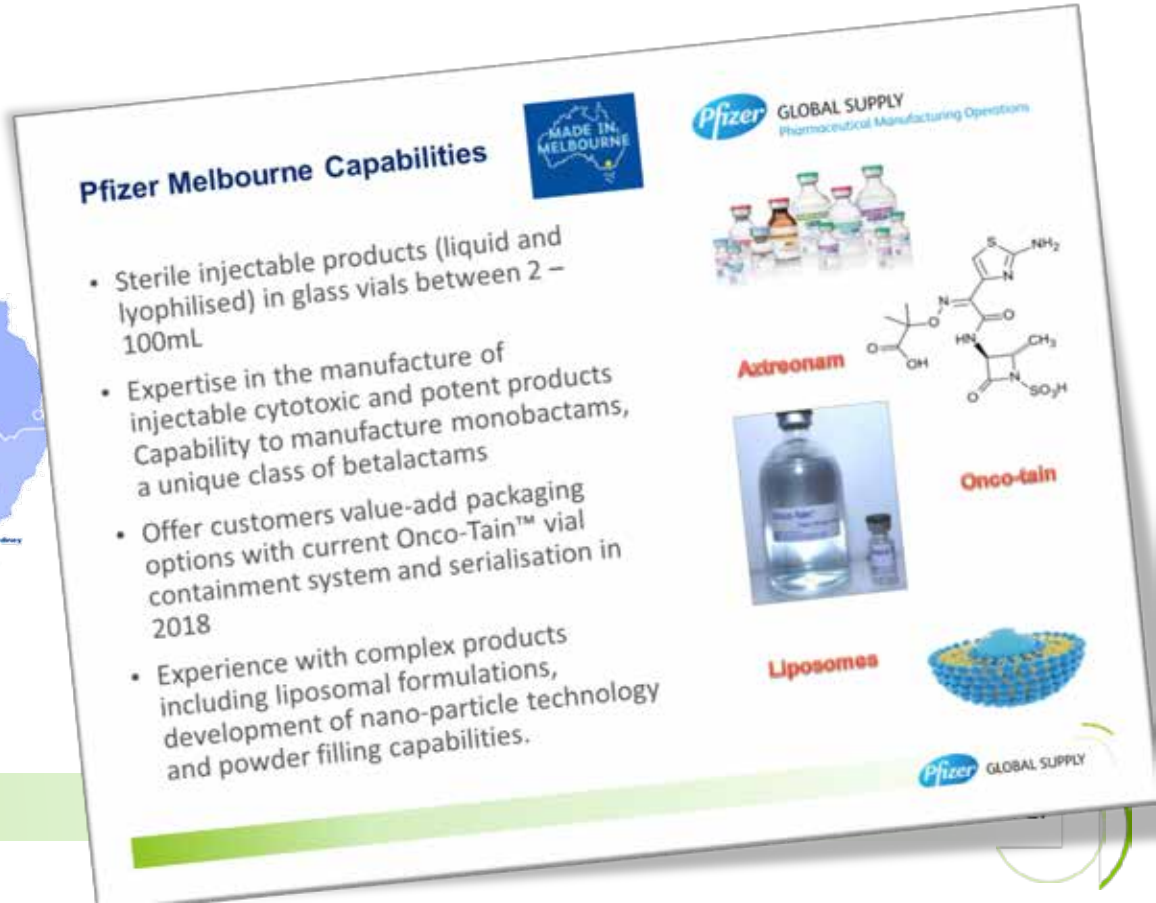
Monday, 6 August 2018

Pfizer Global Supply Melbourne

- Over 100yrs of manufacturing in Australia
- 420+ SKUs to over 60 countries (APAC, EMEA, Americas & Contract Customers)
- Commissioning of additional filling lines
- 2018: Site secures $98 million Pfizer investment



Overview

Inputs for Changing Regulations

Understanding & Interpreting the Change

Methods for assessing the gaps

Addressing the gaps

Please type questions in chat so we can answer them at the end of the training session.

Poll Questions

1. How many people are currently performing gap assessments against PIC/S v13 ?

a) Yet to start

b) Started & gaps Identified

c) Finished & gaps Identified

d) Fully Implemented

e) Not relevant to me

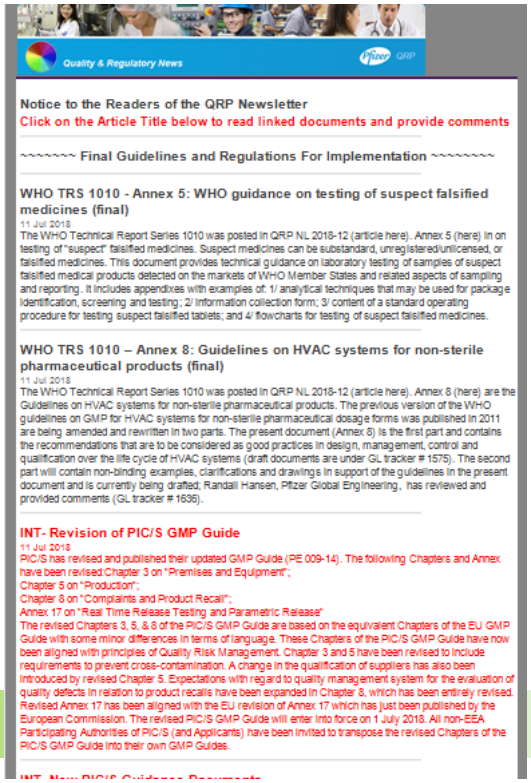
Inputs for Changing Regulations

Pfizer GLOBAL SUPPLY
Pharmaceutical Manufacturing Operations

Receive/Aware of Regulatory Update Notification

- Mail outs vs Google Alerts
- Subscribe to Regulatory Consultations eg TGA, CDER News

- Internal Company Notifications


Quality & Regulatory News

Notice to the Readers of the QRP Newsletter
Click on the Article Title below to read linked documents and provide comments

~~~~~~~ Final Guidelines and Regulations For Implementation ~~~~~~~~

WHO TRS 1010 - Annex 5: WHO guidance on testing of suspect falsified medicines (final)
11 Jul 2018
The WHO Technical Report Series 1010 was posted in QRP NL 2018-12 (article here). Annex 5 (here) in on testing of "suspect' falsified medicines. Suspect medicines can be substandard, unregistered/unlicensed, or falsified medicines. This document provides technical guidance on laboratory testing of samples of suspect falsified medical products detected on the markets of WHO Member States and related aspects of sampling and reporting. It includes appendixes with examples of: 1/ analytical techniques that may be used for package identification, screening and testing; 2/ information collection form; 3/ content of a standard operating procedure for testing suspect falsified tablets; and 4/ flowcharts for testing of suspect falsified medicines.

WHO TRS 1010 – Annex 8: Guidelines on HVAC systems for non-sterile pharmaceutical products (final)
11 Jul 2018
The WHO Technical Report Series 1010 was posted in QRP NL 2018-12 (article here). Annex 8 (here) are the Guidelines on HVAC systems for non-sterile pharmaceutical products. The previous version of the WHO guidelines on GMP for HVAC systems for non-sterile pharmaceutical dosage forms was published in 2011 are being amended and rewritten in two parts. The present document (Annex 8) is the first part and contains the recommendations that are to be considered as good practices in design, management, control and qualification over the life cycle of HVAC systems (draft documents are under GL tracker # 1575). The second part will contain non-binding examples, clarifications and drawings in support of the guidelines in the present document and is currently being drafted. Randall Hansen, Pfizer Global Engineering, has reviewed and provided comments (GL tracker # 1636).

INT- Revision of PIC/S GMP Guide
11 Jul 2018
PIC/S has revised and published their updated GMP Guide (PE 009-14). The following Chapters and Annex have been revised:Chapter 3 on "Premises and Equipment";
Chapter 5 on "Production";
Chapter 8 on "Complaints and Product Recall";
Annex 17 on "Real Time Release Testing and Parametric Release"
The revised Chapters 3, 5, & 8 of the PIC/S GMP Guide are based on the equivalent Chapters of the EU GMP Guide with some minor differences in terms of language. These Chapters of the PIC/S GMP Guide have now been aligned with principles of Quality Risk Management. Chapter 3 and 5 have been revised to include requirements to prevent cross-contamination. A change in the qualification of suppliers has also been introduced by revised Chapter 5. Expectations with regard to quality management system for the evaluation of quality defects in relation to product recalls have been expanded in Chapter 8, which has been entirely revised. Revised Annex 17 has been aligned with the EU revision of Annex 17 which has just been published by the European Commission. The revised PIC/S GMP Guide will enter into force on 1 July 2018. All non-EEA Participating Authorities of PIC/S (and Applicants) have been invited to transpose the revised Chapters of the PIC/S GMP Guide into their own GMP Guides.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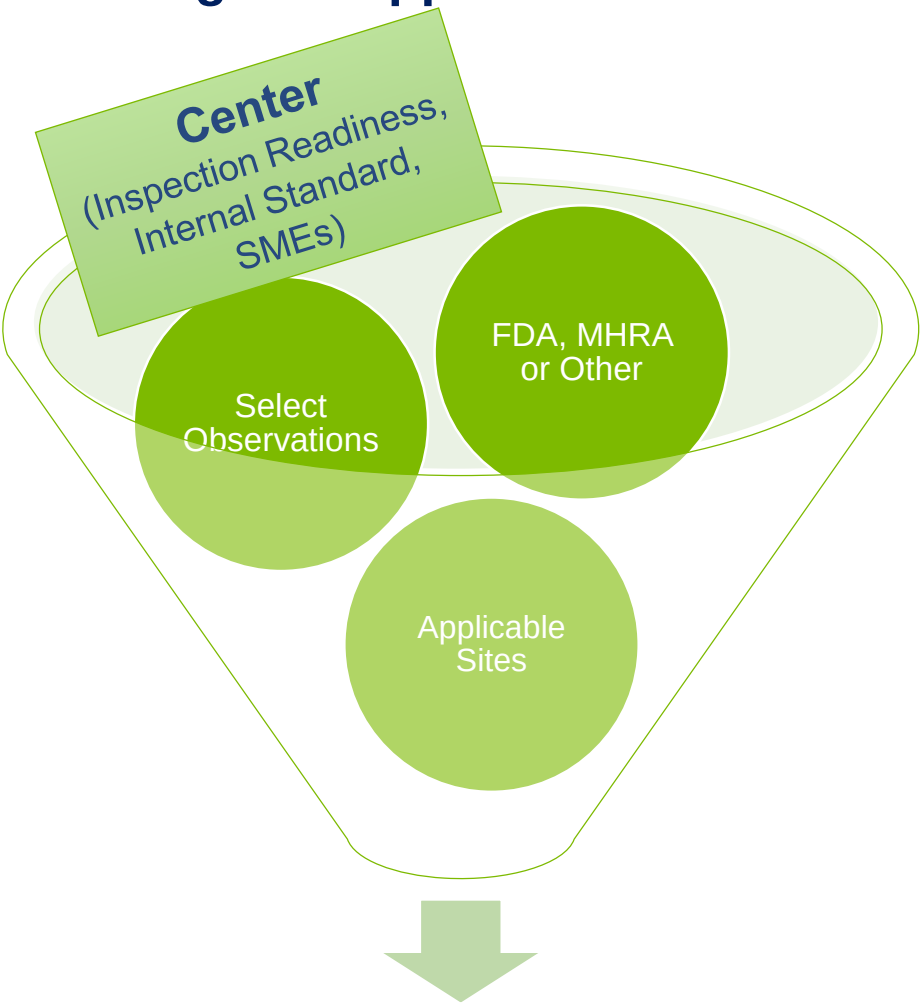
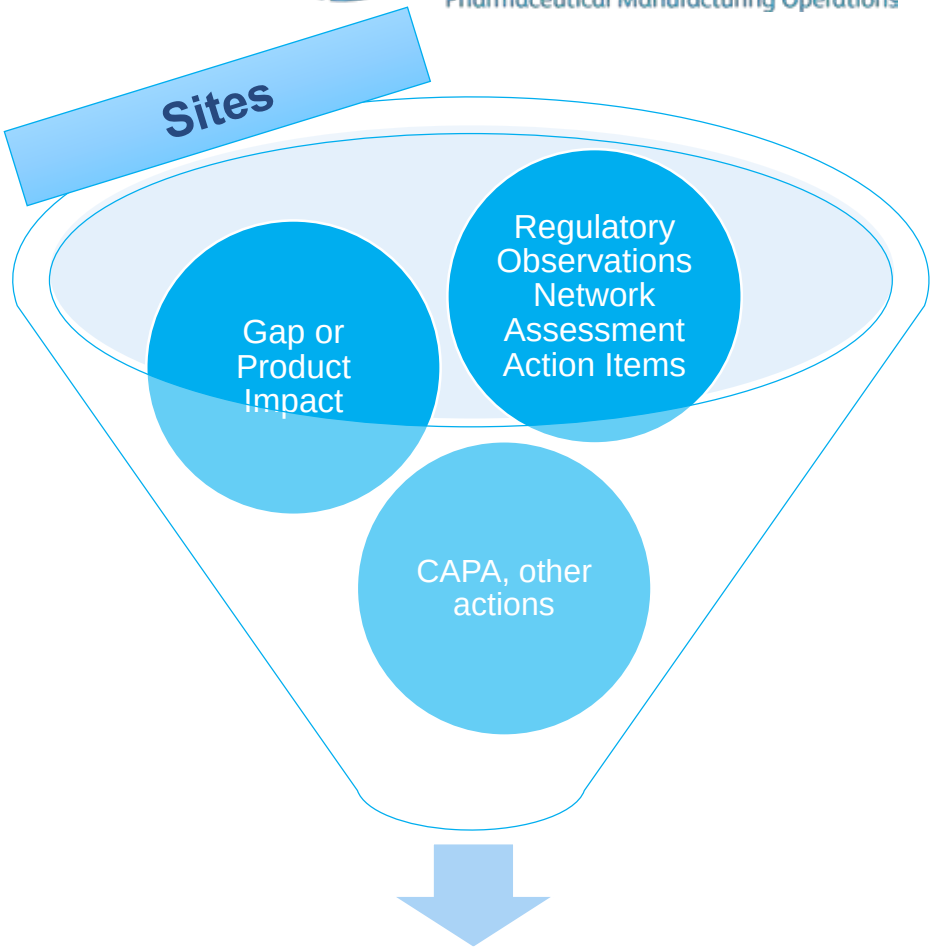
Targeted Approach



Track Action Items



Assessment Complete

Understanding & Interpreting the Change

What is the intent?

Department of Health
Therapeutic Goods Administration

Search TGA

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Industry

- SME Assist
- Regulation basics
- Prescription medicines
- Over-the-counter medicines
- Complementary medicines
- Sunscreens

Home › Industry › Manufacturing therapeutic goods › Manufacturing medicines › PE009-13, the PIC/S guide to GMP for medicinal products

A- A+ Share

PE009-13, the PIC/S guide to GMP for medicinal products

TGA interpretation and expectations for demonstrating compliance

2 January 2018

Print version

PE009-13, the PIC/S guide to GMP for medicinal

Development of a quality manual

Clause 1.7 in PE009-13 requires a Quality Manual (or equivalent document) to be written and maintained. A quality manual or equivalent should be established and should contain the description of the pharmaceutical quality system. The description should include:

- the quality policy
- the scope of the PQS
- identification of the PQS processes, as well as their sequences, linkages and interdependencies. Process maps and flow charts can be useful tools to facilitate depicting PQS processes in a visual manner
- management responsibilities within the PQS

- Consultants
- Industry Events
- Professional Networks

Methods for assessing the gaps

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- Tracking Sheet

- Compliance Gap Assessment Form
  - List Requirement, Provide evidence for compliance, Commit to CAPAs for any gaps, Provide Tracking Date

- Cross functional Team
- Individual Input/Workshops

Poll Questions

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Pharmaceutical Manufacturing Operations

2. If PIC/S v13 has relevance for you in which area are gaps likely to be identified?

a) Premises & Equipment

b) Production

c) Complaints & Product Recall

d) QMS/Documentation

Example of Identified Gap

- Clause 1.7 in PIC/S v13 requires a Quality Manual (or equivalent document) to be written and maintained.
  - Quality Policy
  - Quality Plan
  - Site Master File

- Re-write & Re-instate Quality Manual with links to relevant responsibilities and interaction of the various quality documents.

Addressing the gaps

- Charter/Plan
- Cross functional support, understanding & ownership
- Tracking & Effectiveness
  - Number of clauses assessed
  - Number of gaps/area
  - Open CAPAs
- Budget/Capital
- Procedures/Training