Validation Introduction

Presented by John Montalto

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PharmOut

Regulatory Knowledge, Practically Applied.

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- Bachelor of Science
- Management Diploma
- >15 years of Industry Experience
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Lei Hao

This activity is a "getting to know you" exercise:

- Introduce yourself
- Validation experience/exposure

5 min/?

Course structure

Course objectives

- PIC/S Annex 15 Qualification and validation
- Process validation
- Cleaning validation considerations

Activity

- With the person next to you, discuss the following:

- Define the term 'Validation'
- What does 'Quality' mean to you?
- What do you expect from a validation program?

- Contribute to the group discussion

The history of validation

The concept of validation was initially proposed in the mid-1970's

- Several significant issues with high volume aseptic products were realised
- The early concept of validation was to verify the robustness of the manufacturing processes
- Two US FDA regulators Ted Byers and Bud Loftus are recognised as having significant influence in validation

The history of validation

Where the early concept of validation was to verify the robustness of the manufacturing processes, later efforts spread to:

- Production environments
- Media fill processes
- Purified water production
- Equipment sanitation
- Facility services

The history of validation

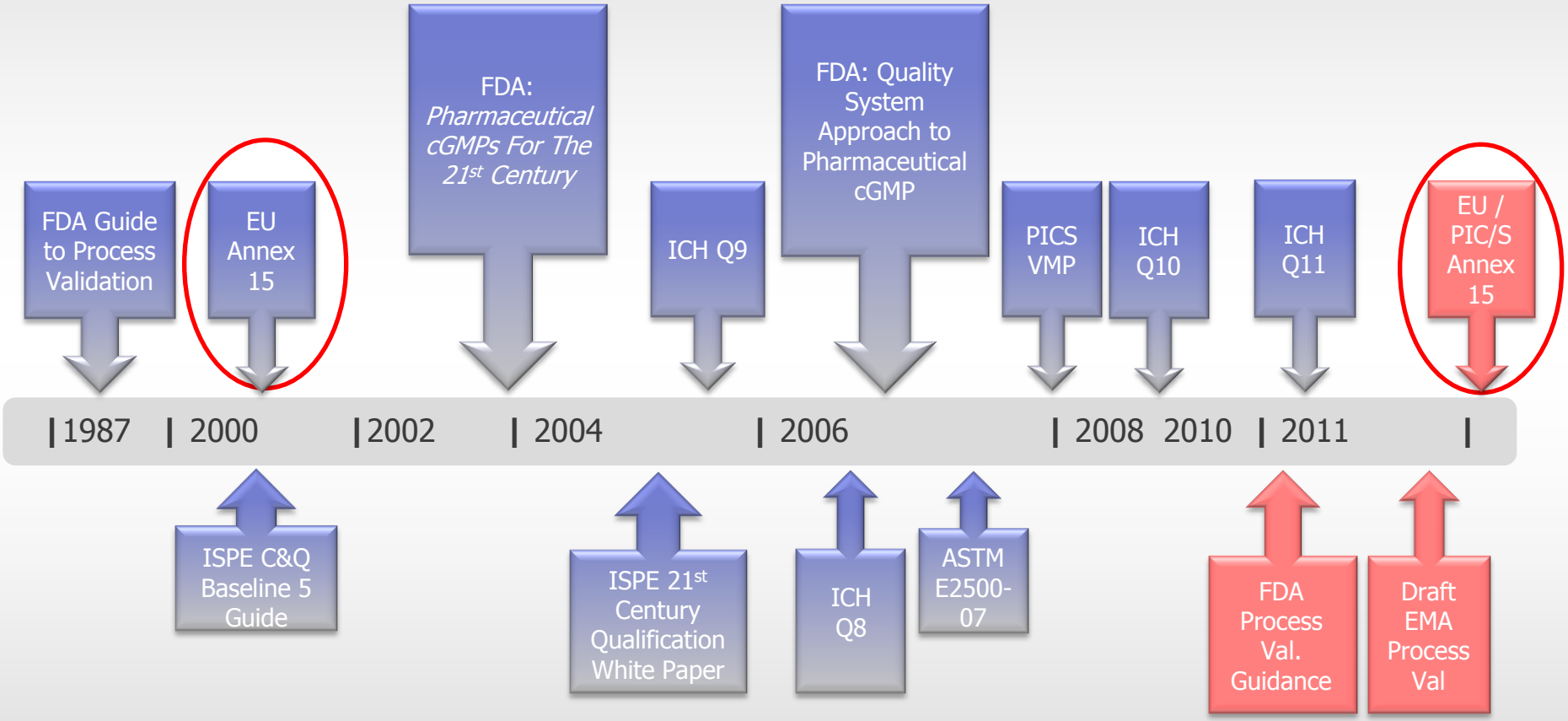
Validation activities were (and still are) based on engineering practices.

- For example, how large, complex items of equipment are manufactured, tested, delivered and accepted to fulfil contractual obligations.
- More recently in 2005 the concept of validation spread to cold chain distribution processes.

The history of validation

Validation continues to evolve, but the core attributes remain consistent:

Influences on validation



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Top 10 Most Frequently Cited GMP Deficiencies (PIC/S Member Authorities) (July 2010 – June 2011)

1. Documentation on manufacturing
2. Design & maintenance of premises
3. Documentation – quality systems elements/procedures
4. Personnel issues – training
5. Design & maintenance of equipment
6. Cleaning validation
7. Process validation
8. Product Quality Review
9. Supplier & contractor audit
10. Calibration of measuring & testing equipment

Source: Presentation by H. Smallenbroek (IGZ, Netherlands) & B. Meow Hoe (HSA, Singapore) on "Review of similarities & differences of top 10 deficiencies cited by PIC/S participating authorities", PIC/S Seminar, Cape Town, Nov'11.
Will be repeated (& further discussed) at PDA-PICS Workshop, Geneva 9-10 May 2012.

Top 10 Most Severe GMP Deficiencies (PIC/S Member Authorities) (July 2010 – June 2011)

1. Design & maintenance of premises
2. Contamination, potential for (chemical, physical, microbial)
3. Design & maintenance of equipment
4. Sterility assurance
5. Batch release procedures
6. Process validation
7. Cleaning validation
8. Investigation of anomalies
9. Documentation – quality systems elements/procedures
10. Regulatory issues – noncompliance with marketing authorisation

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Top Ten GMP Deficiencies found by MHRA (UK) (from MHRA web site Aug 2011)

1. Investigation of Anomalies
2. Quality management
3. Quality management (Change Control)
4. Validation Master Plan & Documentation
5. Corrective Action/Preventative Action (CAPA)
6. Complaints and Product Recall
7. Documentation
8. Equipment Validation
9. Quality Management –Product Quality Review
10. Investigation of Anomalies - OOS

Slide 15

Why validate?

Validation is:

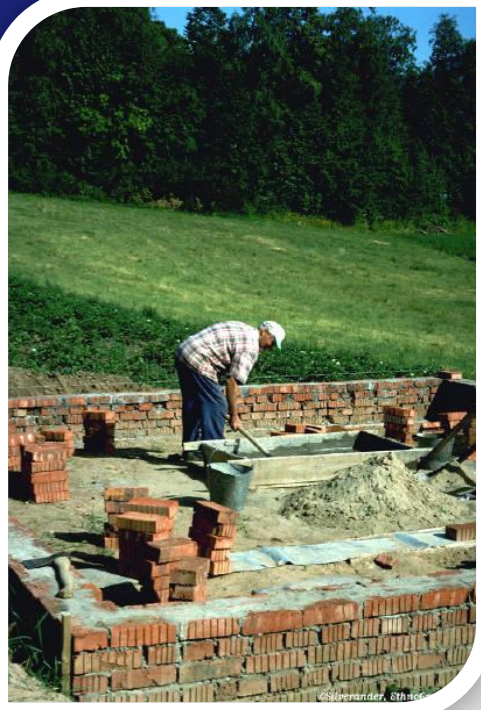
"Establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes."

- A properly designed system will provide a high degree of assurance that every step, process, and change has been properly evaluated before its implementation.

- Testing a sample of a final product is not considered sufficient evidence that every product within a batch meets the required specification

Laying the foundations

Understanding the principles of validation is the foundation for ensuring the process produces a quality product consistently.



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Thank you for your time. Questions?

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