ICH
harmonisation for better health

Comparability

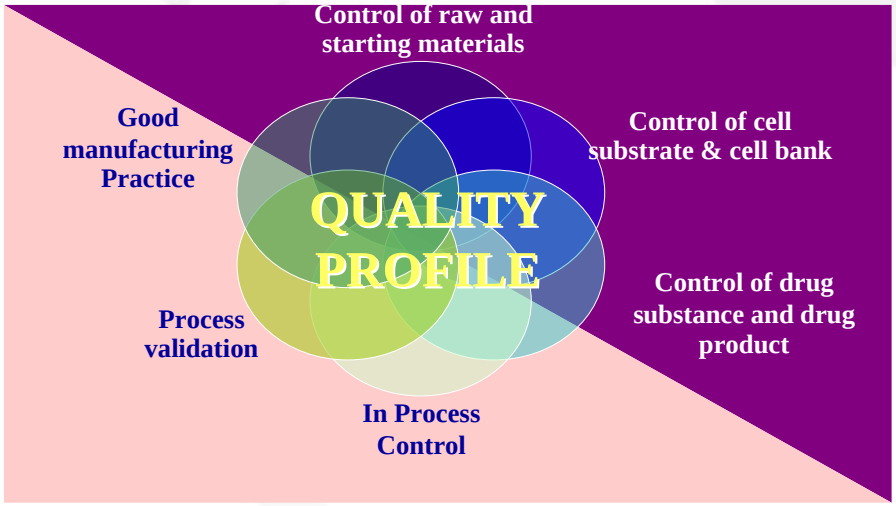
K. Ho
Afssaps, France

Disclaimer:

- **The information within this presentation is based on the presenter's expertise and experience, and represents the views of the presenter for the purposes of a training workshop.**

Quality assessment

Product A / Process A

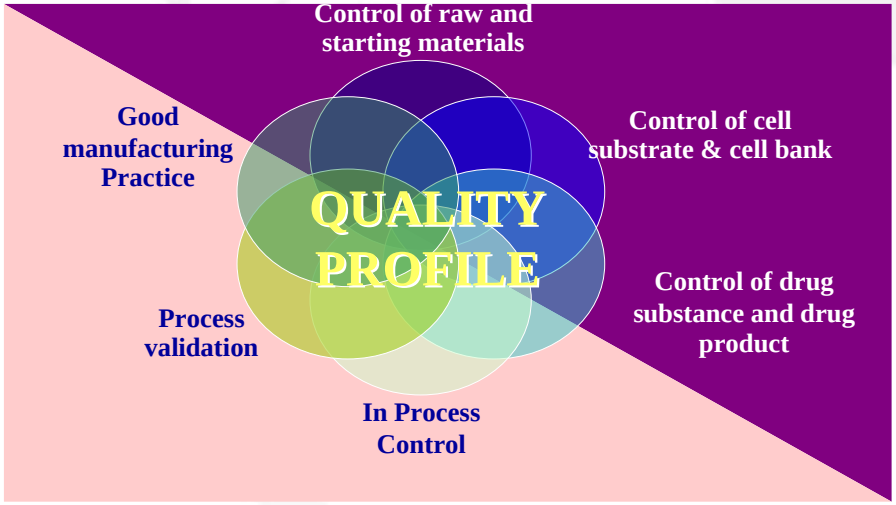


Safety & Efficacy profiles

A

Quality assessment

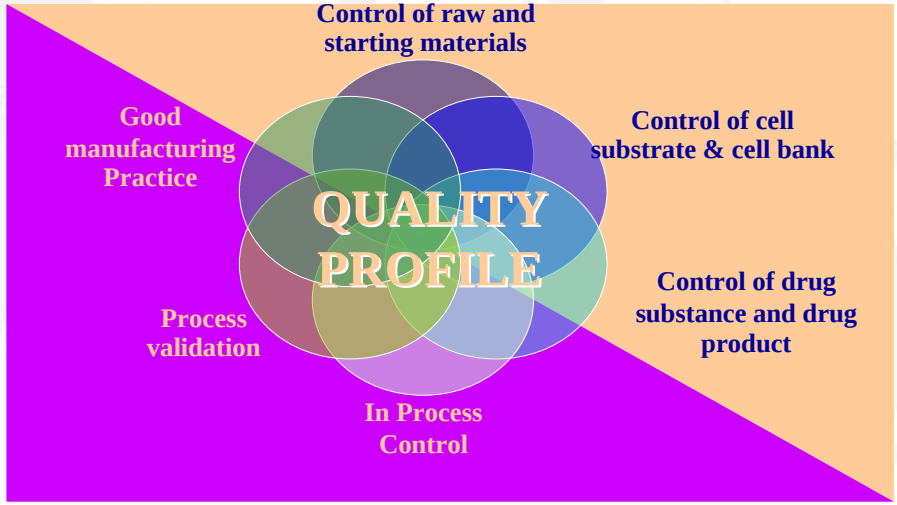
Product A1 / Process A1



Safety & Efficacy profiles

A1

Product A2 / Process A2



Safety & Efficacy profiles

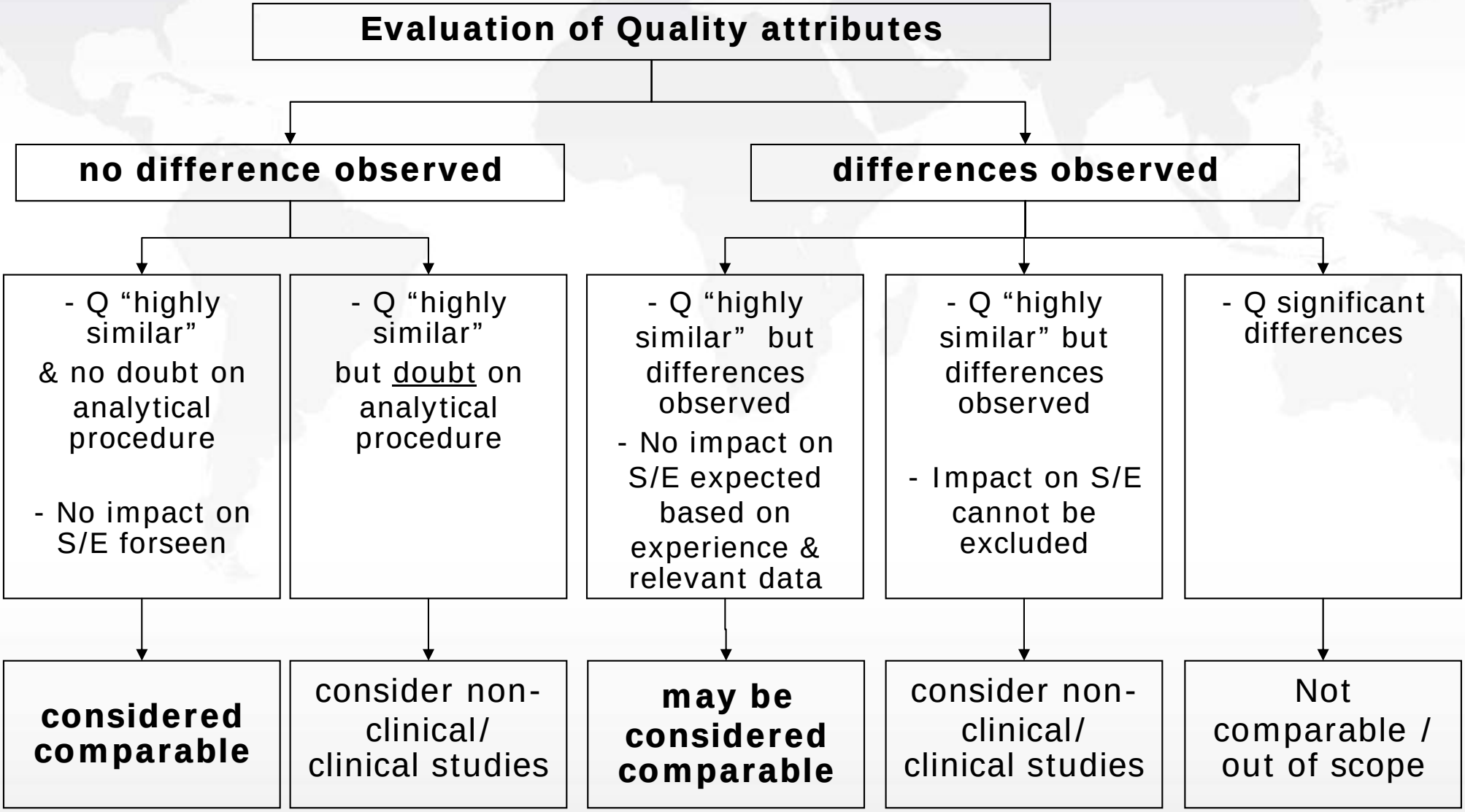
A2

Comparability (ICH Q5E)

- **Comparability exercise:**
  - Goal: to ascertain that pre- and post-change drug product is comparable in terms of quality, safety, and efficacy.

- **Demonstration of comparability:**
  - Does not necessarily mean that the quality attributes of the pre-change and post-change products are identical but highly similar
  - Ensure that differences in quality attributes have no adverse impact upon safety or efficacy of the drug product.
  - Based on combination of analytical testing, biological assays ± nonclinical and clinical data

Comparability (ICH Q5E)



Comparability (ICH Q5E)

- **Comparability exercise: Extent of data depend on:**
  - Step where the change is introduced
  - Potential impact of the change
  - Suitability of analytical techniques
  - Knowledge of the product & relationship between quality attributes and safety and efficacy
- **Determination of comparability**
  - Combination of analytical testing, biological assays, non-clinical and clinical data in some cases
  - Demonstration of highly similar Quality profiles
    - validation batches, recent batches
    - historical results, sample library
    - stability profile
  - Justification of the suitability of the methods
    - appropriately selected to maximize the potential of detecting differences
    - specification: may not be sufficient
    - characterization: may be required

Comparability (ICH Q5E)

- **Manufacturing process considerations**
  - Well defined process + controls :
    - Assurance that product is produced in a consistent basis
    - Suitability of controls: confirm that process controls in the modified process provide similar or more effective control of the product quality, compared to the original process

Comparability (ICH Q5E)

- **Comparability exercises during development:**
  - Generally performed to demonstrate that nonclinical / clinical data generated with pre- and post-change products are applicable
  - Takes into consideration stage of development, availability of analytical procedures and the available experience
    - If change introduced before non-clinical studies: generally not an issue
    - If introduced in late stages: may be as comprehensive and thorough as the one conducted for an approved product

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Thank You!