Module 0

Overview of Training Modules

ICH Q3D Elemental Impurities

Disclaimer:
This presentation includes the authors' views on Elemental Impurities theory and practice.
The presentation does not represent official guidance or policy of authorities or industry.

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

Legal Notice

Principles for developing training materials

- Intended to provide clarity on key aspects of the guideline in order to facilitate a harmonized interpretation and implementation by industry and regulators in the ICH and non-ICH regions
- Modular approach:
  - Overview (Module 0)
  - Modules 1-7 on key safety and quality topics
  - Module 8: Three case studies illustrating an approach to presenting the risk assessment
  - Module 9: Frequently Asked Questions
- Elaborate on key principles of the guideline
- Not intended to provide templates for addressing the Q3D recommendations.
- Training material does not provide additional guidance beyond Q3D

Overview of the Guideline

- Main body, references and glossary (pages 1-17)
- Appendix 1: Method for Establishing Exposure Limits (pages 18-20)
- Appendix 2: Established Permitted daily exposures (PDEs) for Elemental Impurities by oral, parenteral and inhalation routes of administration (pages 21-22)
- Appendix 3: Individual Safety Assessments for 24 elements (pages 23-67)
- Appendix 4: Illustrative Examples (pages 68-73)

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Training Modules

1. How to Apply Q3D Concepts to Routes of Administration, not addressed in Q3D
2. Justification for Elemental Impurity Levels Higher than an Established PDE
3. Application of Q3D concepts to determining safe levels of elements not included in Q3D
4. Large Volume Parenterals
5. Risk Assessment
6. Control of Elemental Impurities
7. Converting between PDEs and Concentrations
8. Case Studies
9. FAQs

Training Modules

1. How to Apply Q3D Concepts to Routes of Administration, not addressed in Q3D
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Toxicology

4. Large Volume Parenterals
5. Risk Assessment
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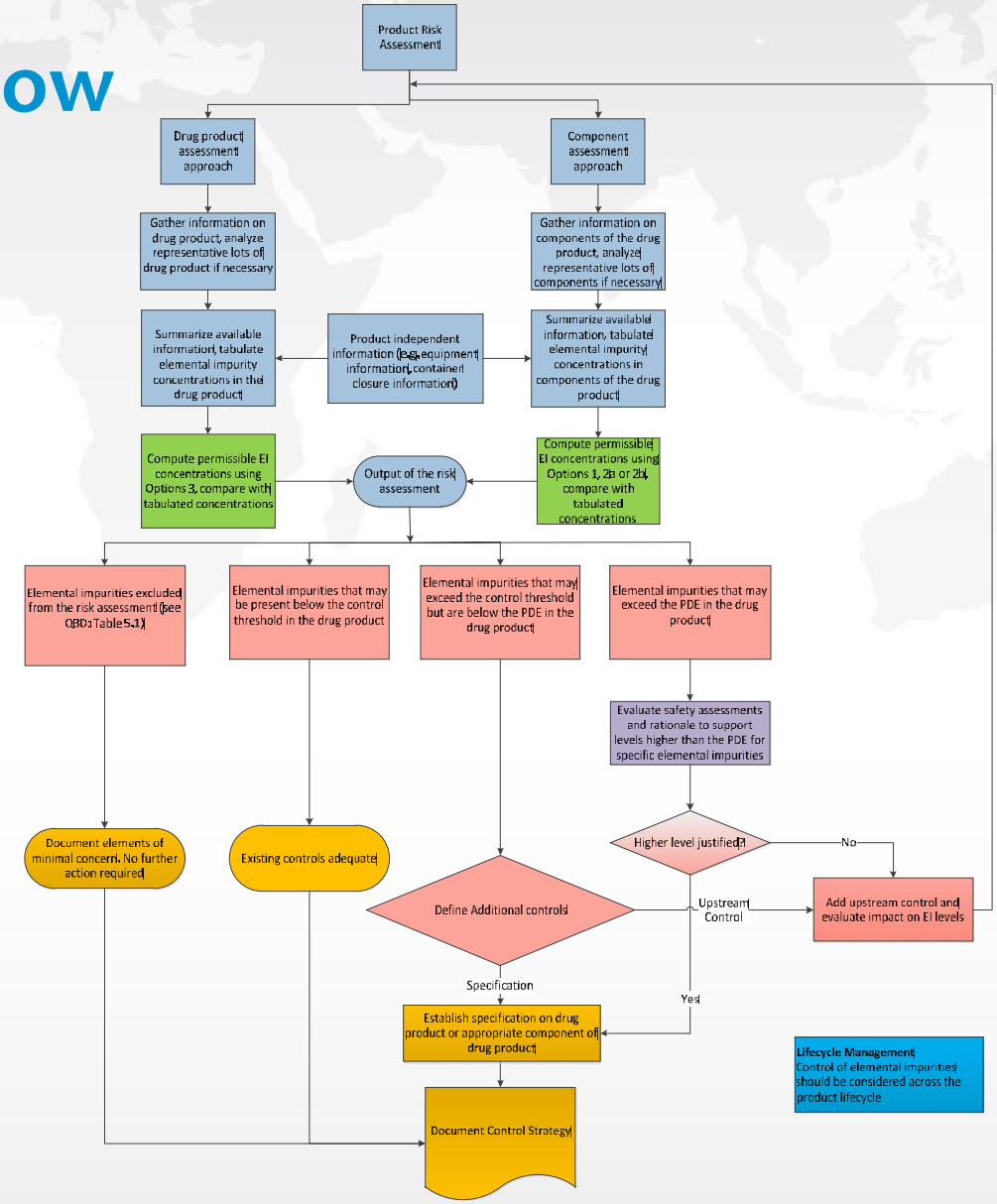
7. Converting between PDEs and Concentrations

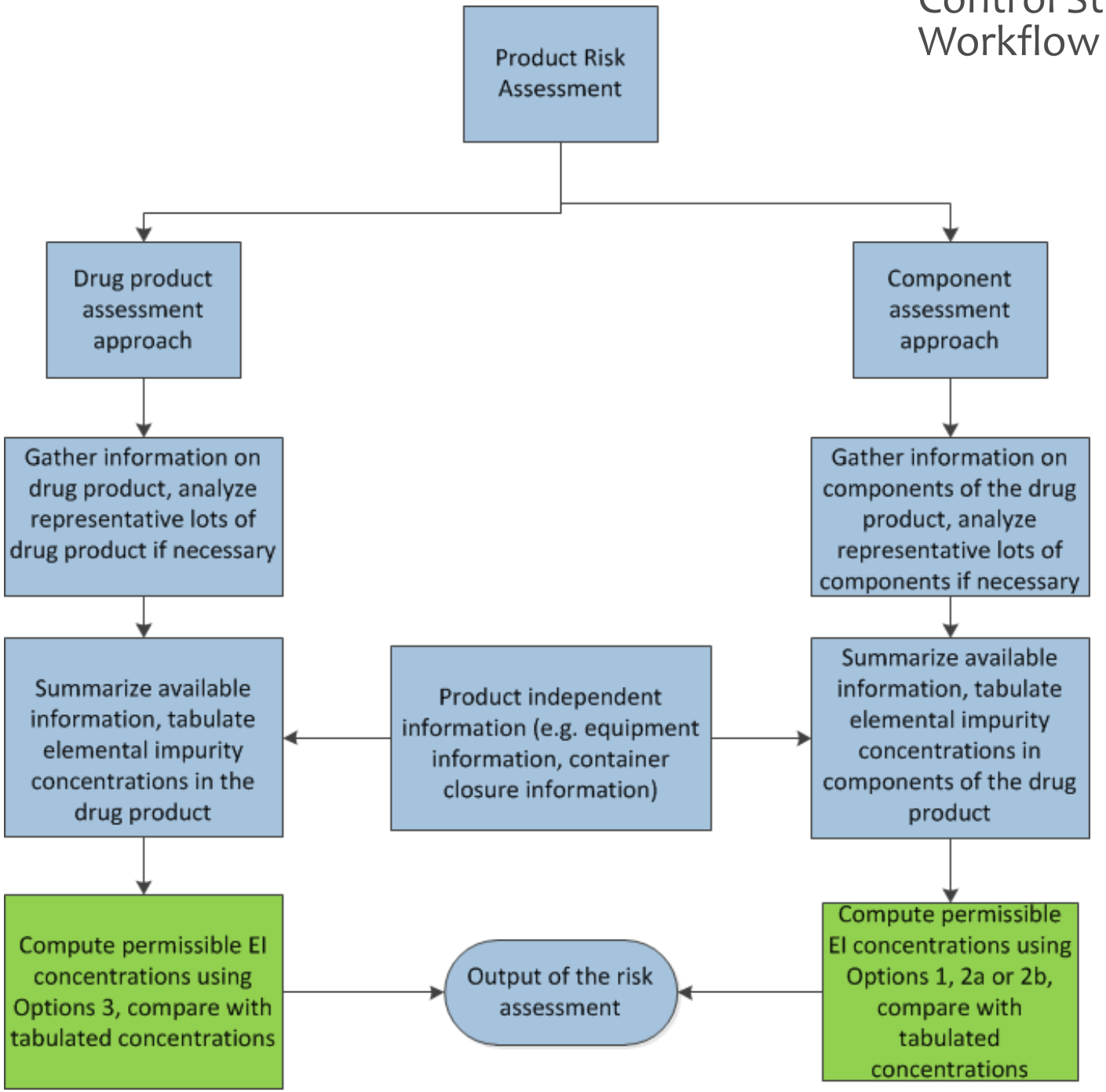
Chemistry

8. Case Studies
9. FAQs

Consolidated Workflow



Control Strategy Workflow



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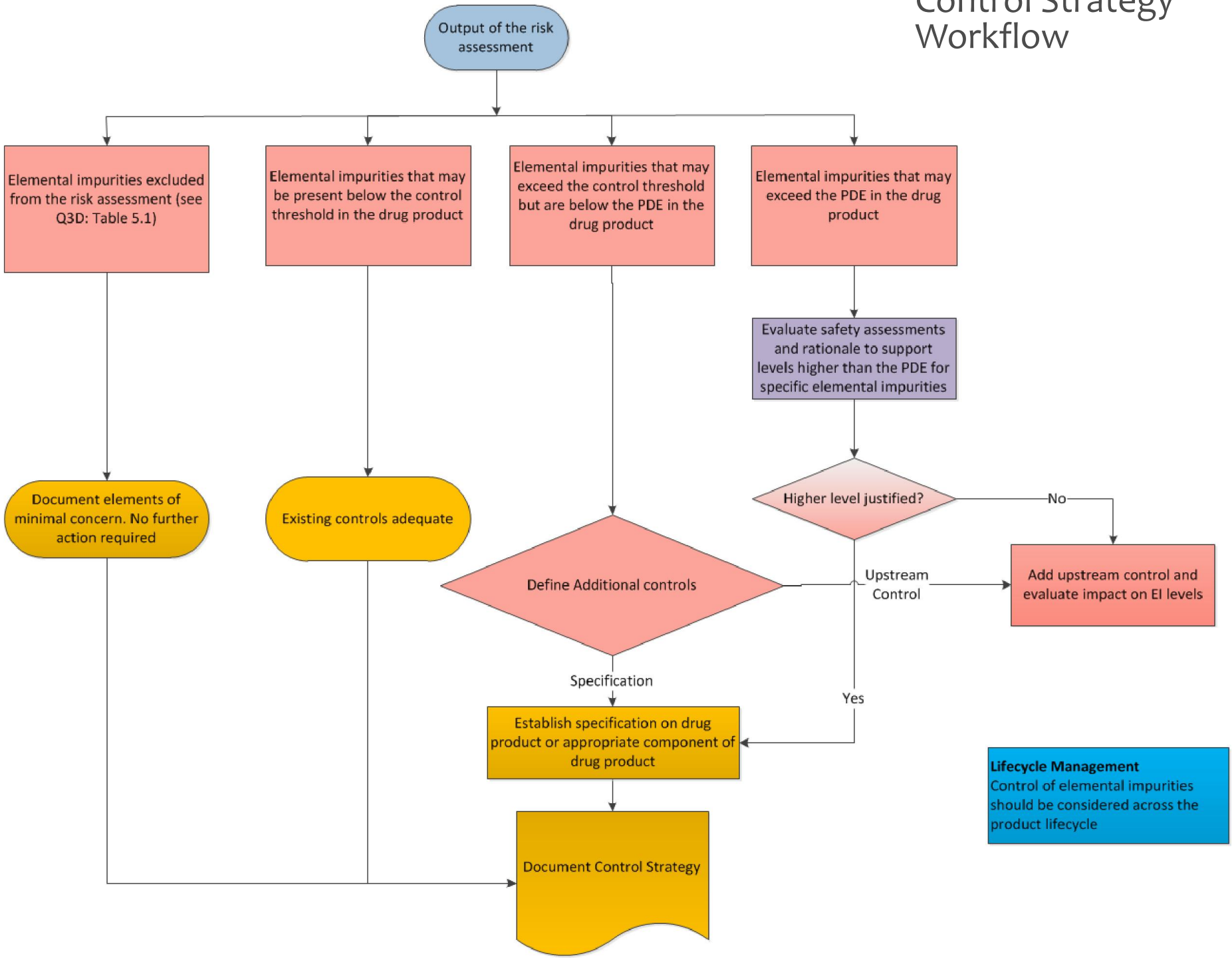

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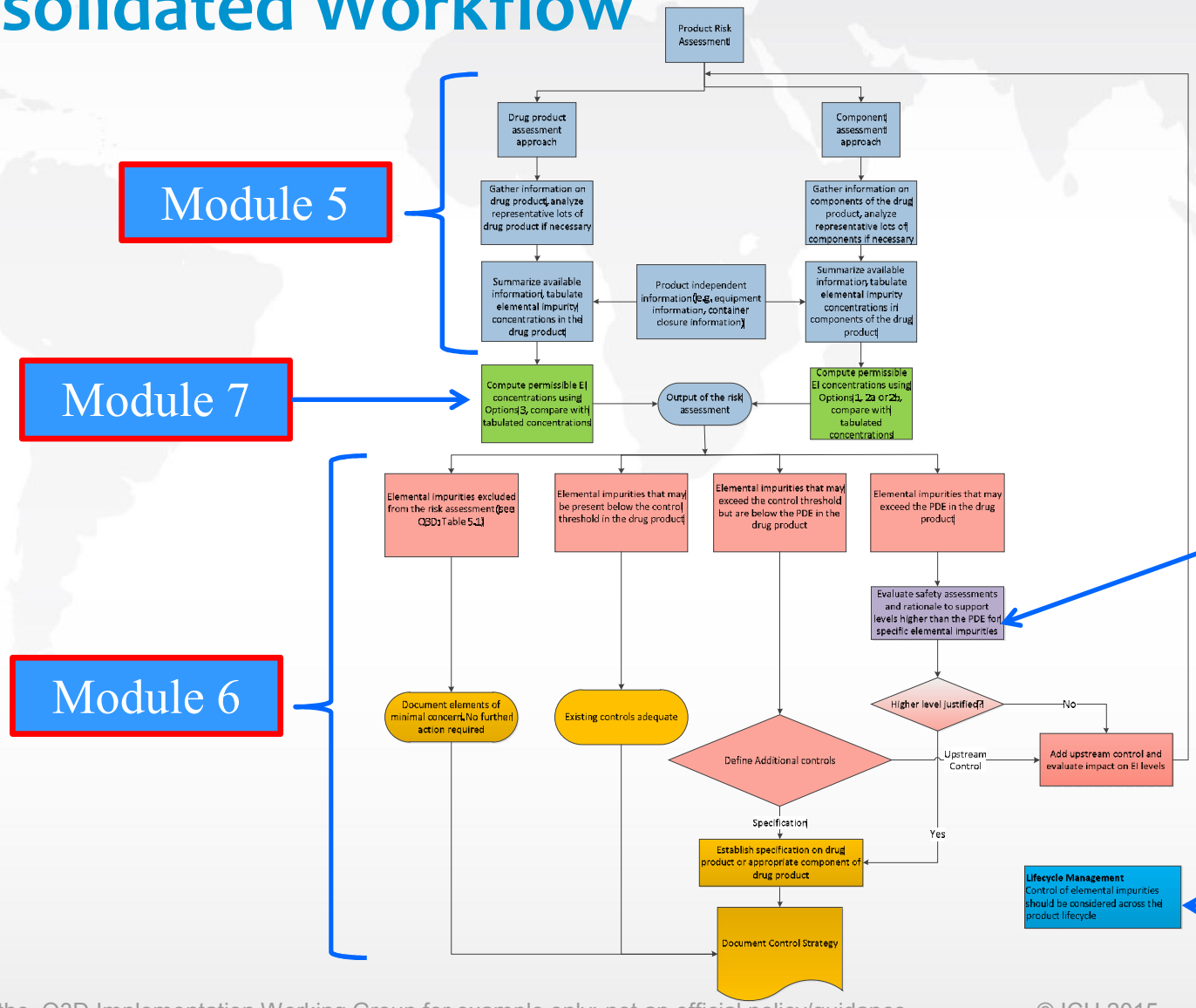

Module 9: Frequently Asked Questions

- **Sources of FAQs**
  - Public comments on Step 2b document
  - Constituents, referred to Q3D EWG through industry representatives
  - Other industry groups
- **FAQs include**
  - Common questions that could not be addressed in the Guideline
  - Questions related to how decisions were made during development of Q3D
  - Examples
    - Why are herbal products out of scope?
    - How did the EWG select the 24 elements (USP and EMA Guideline on Residual Catalysts have fewer elements in their documents).
    - Why is aluminum not included?