

Module 0

Overview of Training Modules

ICH Q3D Elemental Impurities

Disclaimer:

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

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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)

Table of Contents

1. Introduction
 2. Scope
 3. **Safety Assessment of Potential Elemental Impurities**
 - 3.1 Principles of the Safety Assessment ...
 - 3.2 Other Routes of Administration **Module 1**
 - 3.3 Justification for Elemental Impurity Levels Higher than an Established PDE
 - 3.4 Parenteral Products **Module 2**
- Module 4: Large Volume Parenterals**
4. **Element Classification**

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- 5. Risk Assessment and Control of Elemental Impurities Module 5
- 6. Control of Elemental Impurities Module 6
- 7. Converting between PDEs and Concentration Limits Module 7
- 8. Speciation and other Considerations
- 9. Analytical Procedures
- 10. Lifecycle Management

Appendix 1: Method for Establishing Exposure Limits

Module 3: Acceptable exposures for elements without a PDE

Module 8: Case Studies

Module 9: Frequently Asked Questions

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**

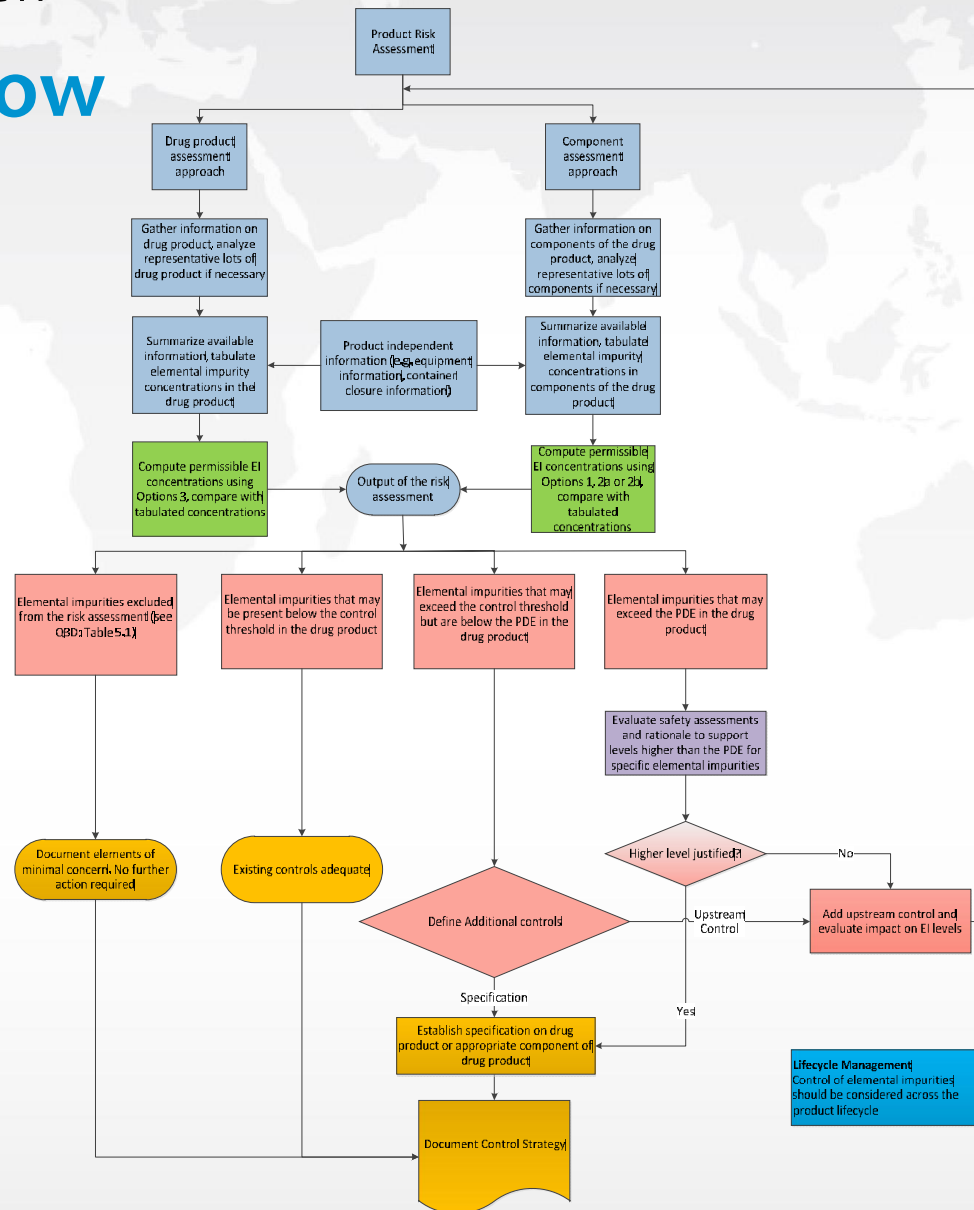
Training Modules

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

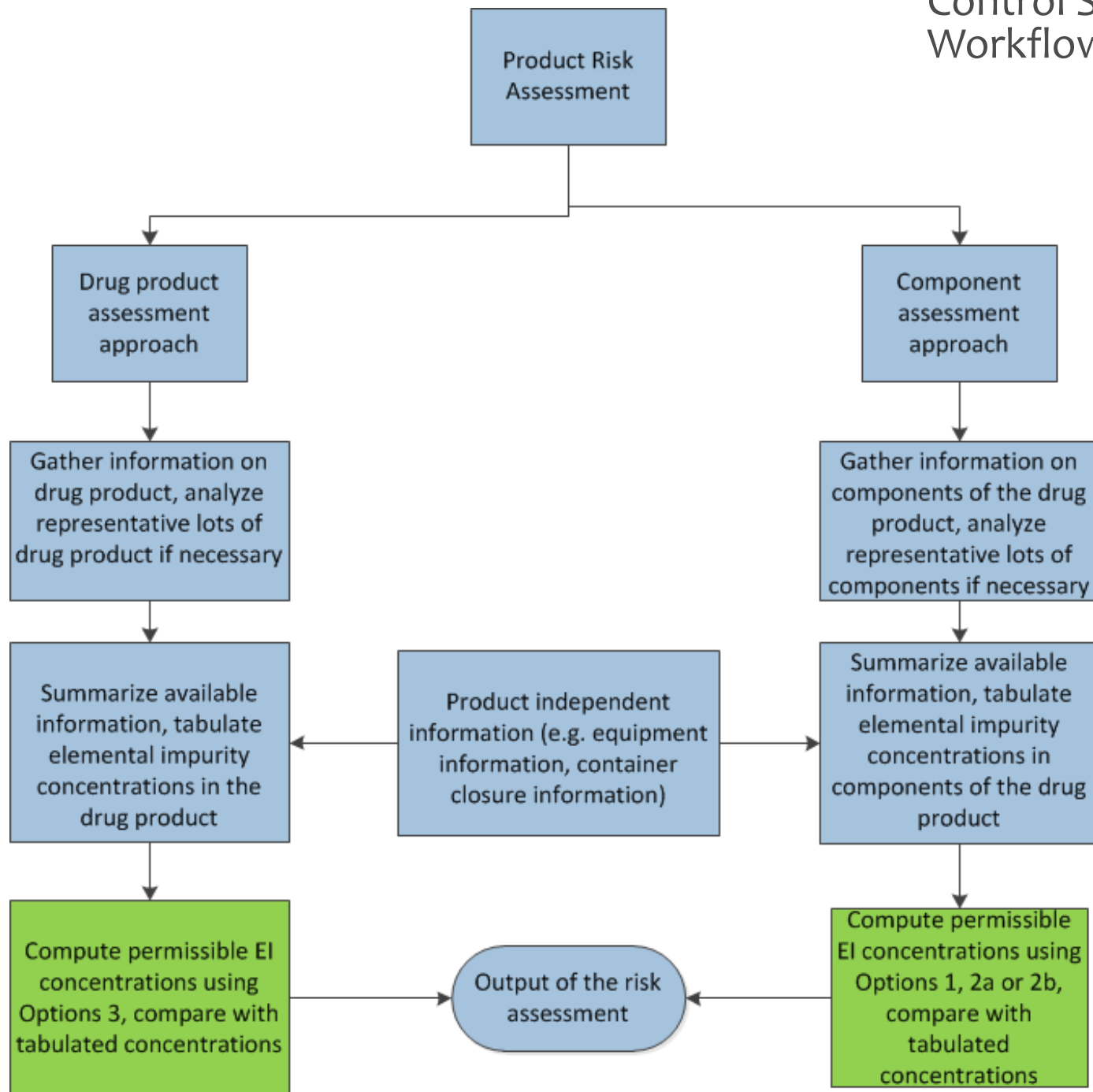
Toxicology

Chemistry

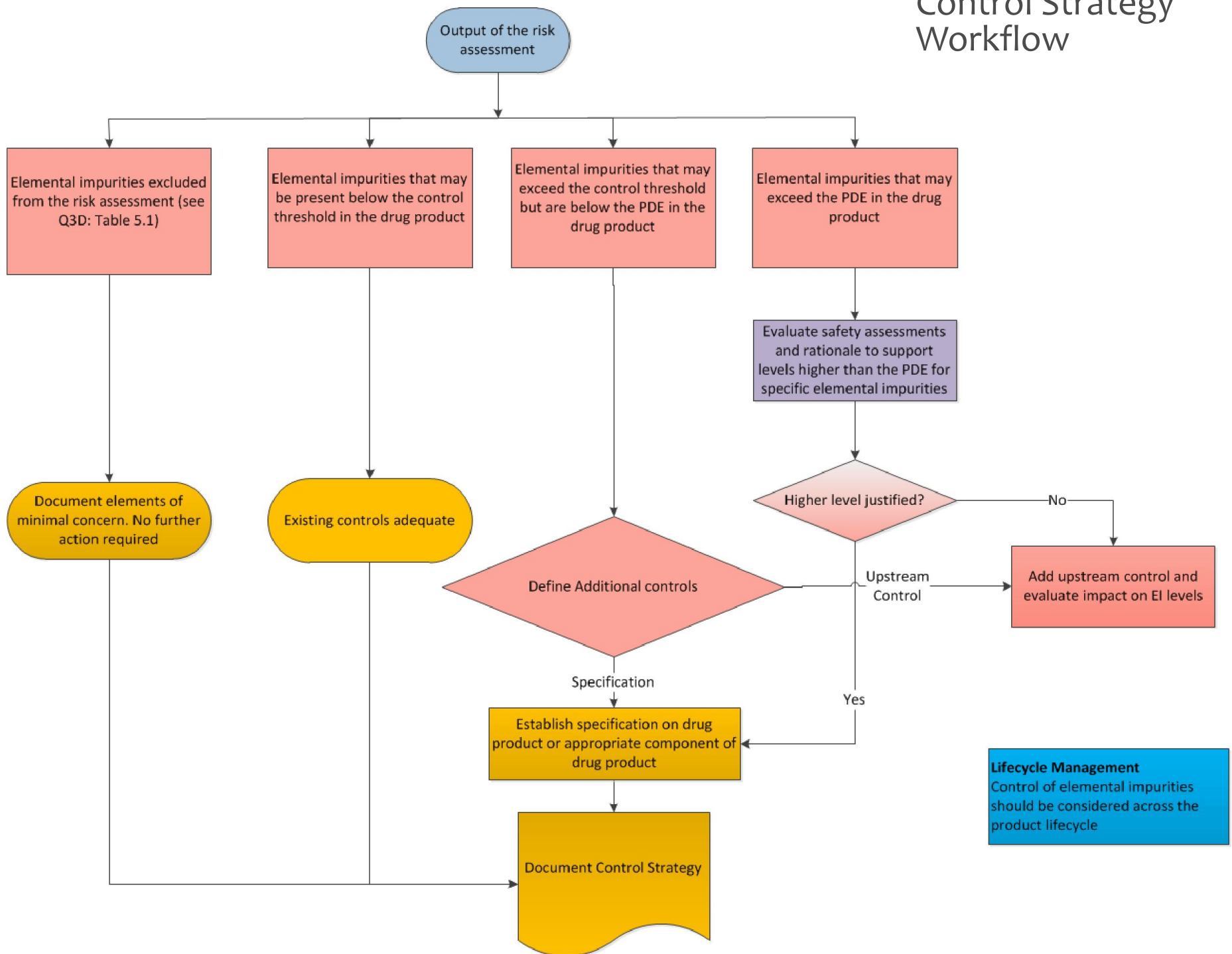
Consolidated Workflow



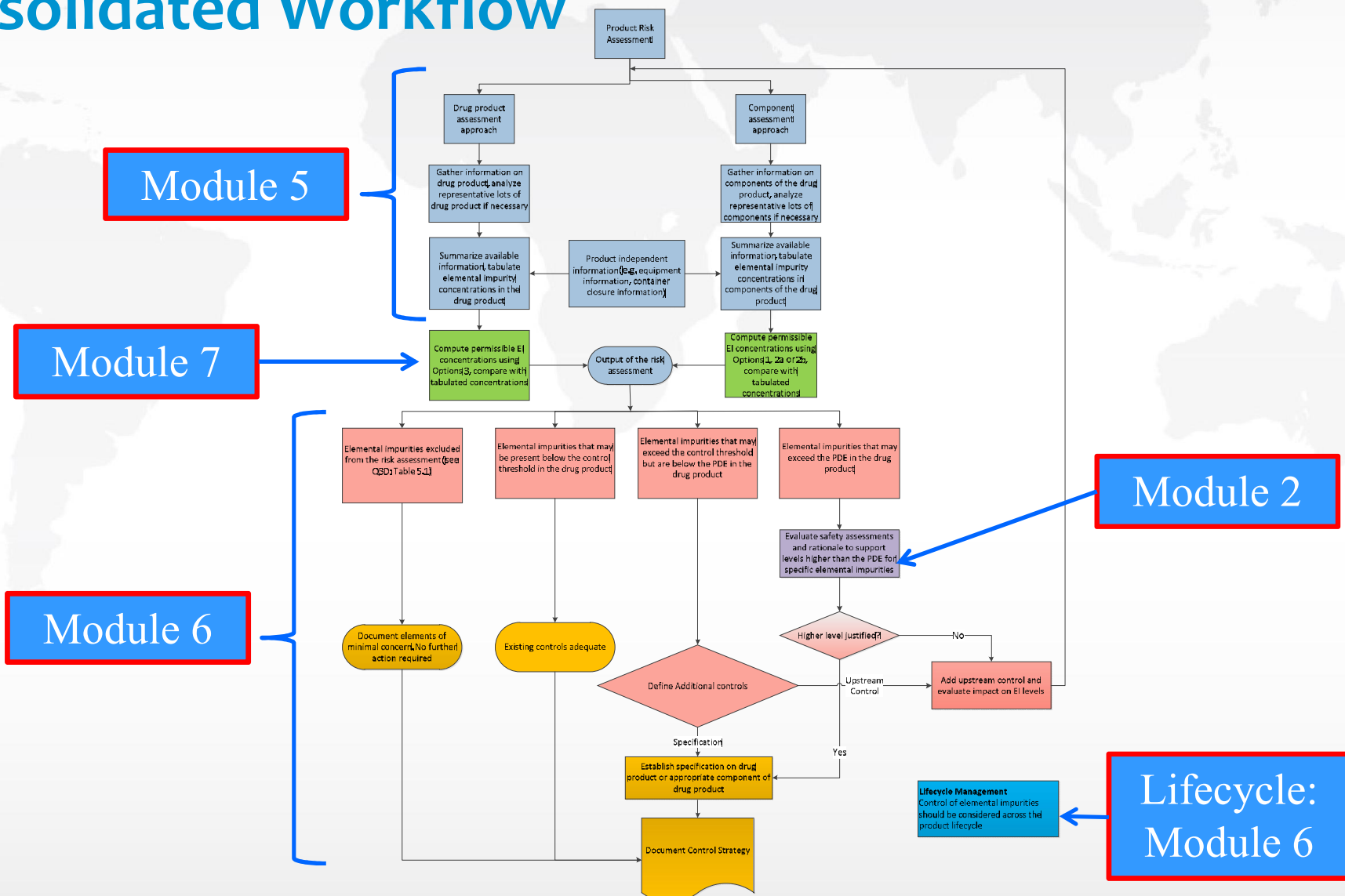
Control Strategy Workflow



Control Strategy Workflow



Consolidated Workflow



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?