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An Industry Perspective on Managing Specific Elements in Public Standards

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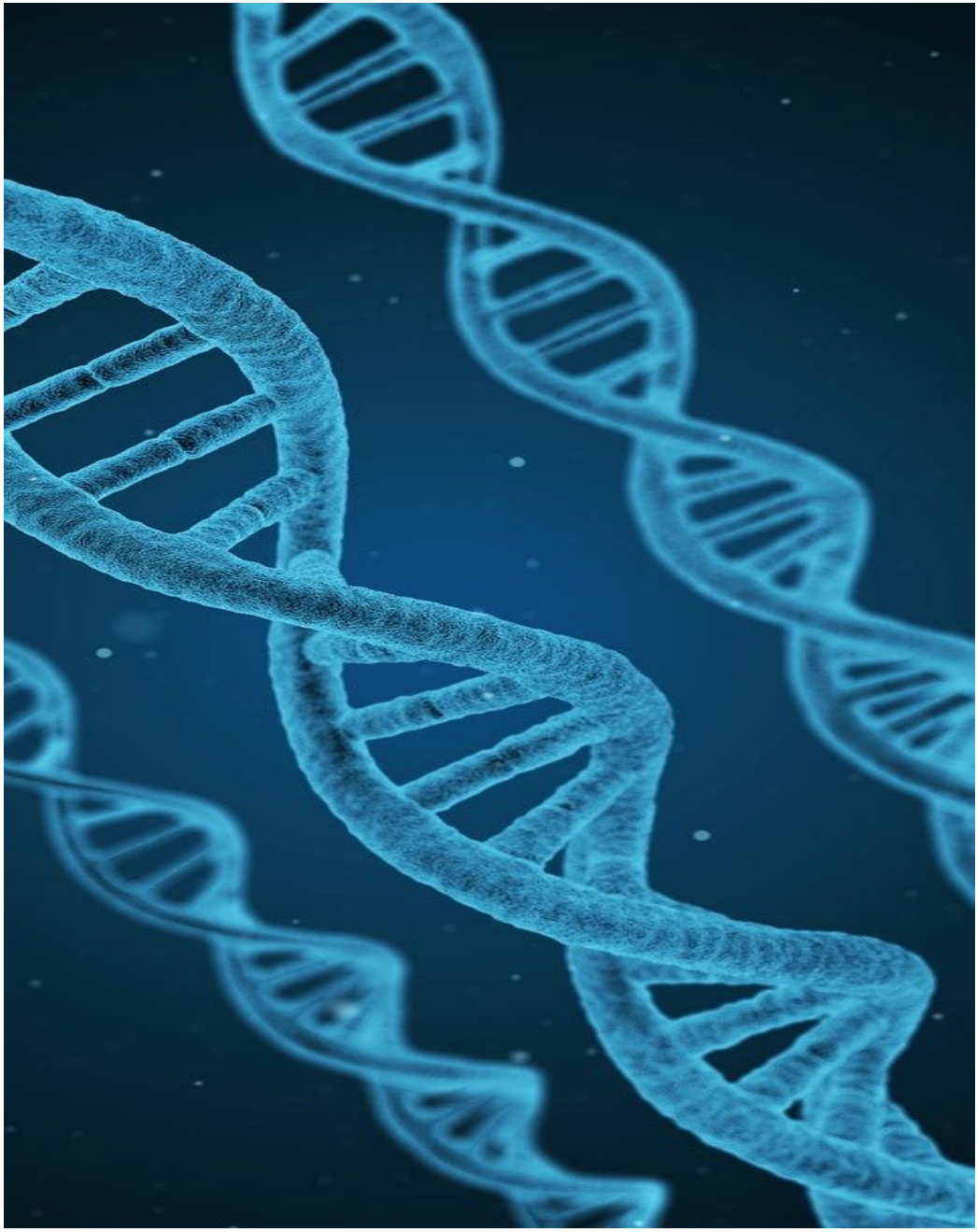
Public

Discussion Outline

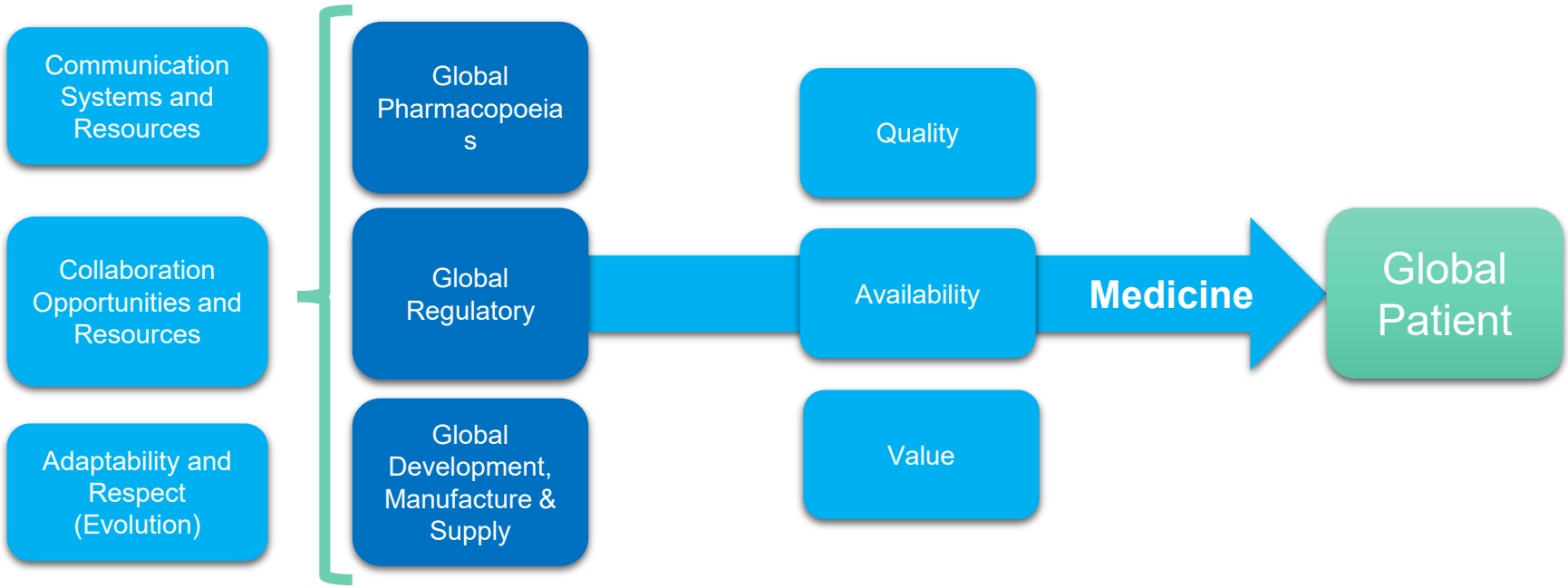
1. Evolution
2. Development
3. Opportunities
4. Challenges

Evolution



Evolution

- Serving the patients
- Safe and effective medicine provided through a reliable and efficient system
- Foundation of working together and understanding our impact on the common goal of serving the patient



Evolution

1. Today relative to past – Global Industry
   - Increased processes
   - Increased dosage forms
   - Increased complexity (Biotherapeutics)
   - Increased Specificity (Methods)
   - Increased Accuracy (Methods and acceptance criteria)
   - Material/Product quality profile becomes more of a manufacturing fingerprint

2. Future
   - New innovations (Medicine, Drug Delivery, Manufacturing, Analysis)
   - Improve time between establishing safe/effective medicine and patient access

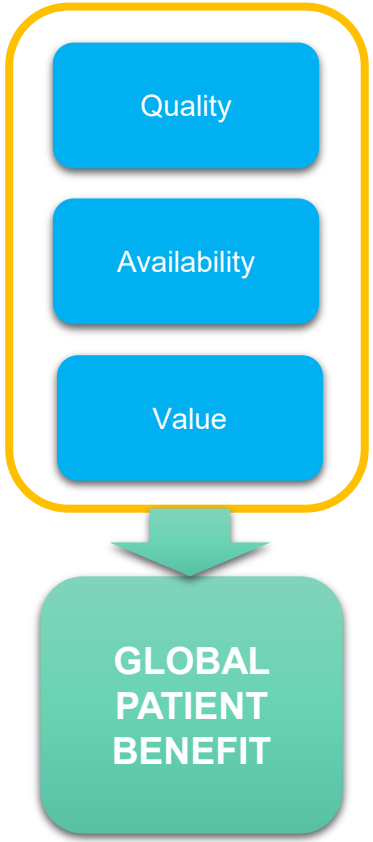
Evolution

1. Today relative to past – Global Regulatory and Pharmacopoeia
   - Increased standard sources (#Active Organizations)
   - Increased activities (Rate of change)
   - Increase challenge to establish a single fixed standard
   - Increased complexity of standards
     - Methods; Theory; Equipment Qualification; Etc.
   - Increased complexity of standard application
     - Alternative methods; Method verification; Regulatory variations
2. Future
   - Increased communication, collaboration/harmonization and flexibility

Evolution

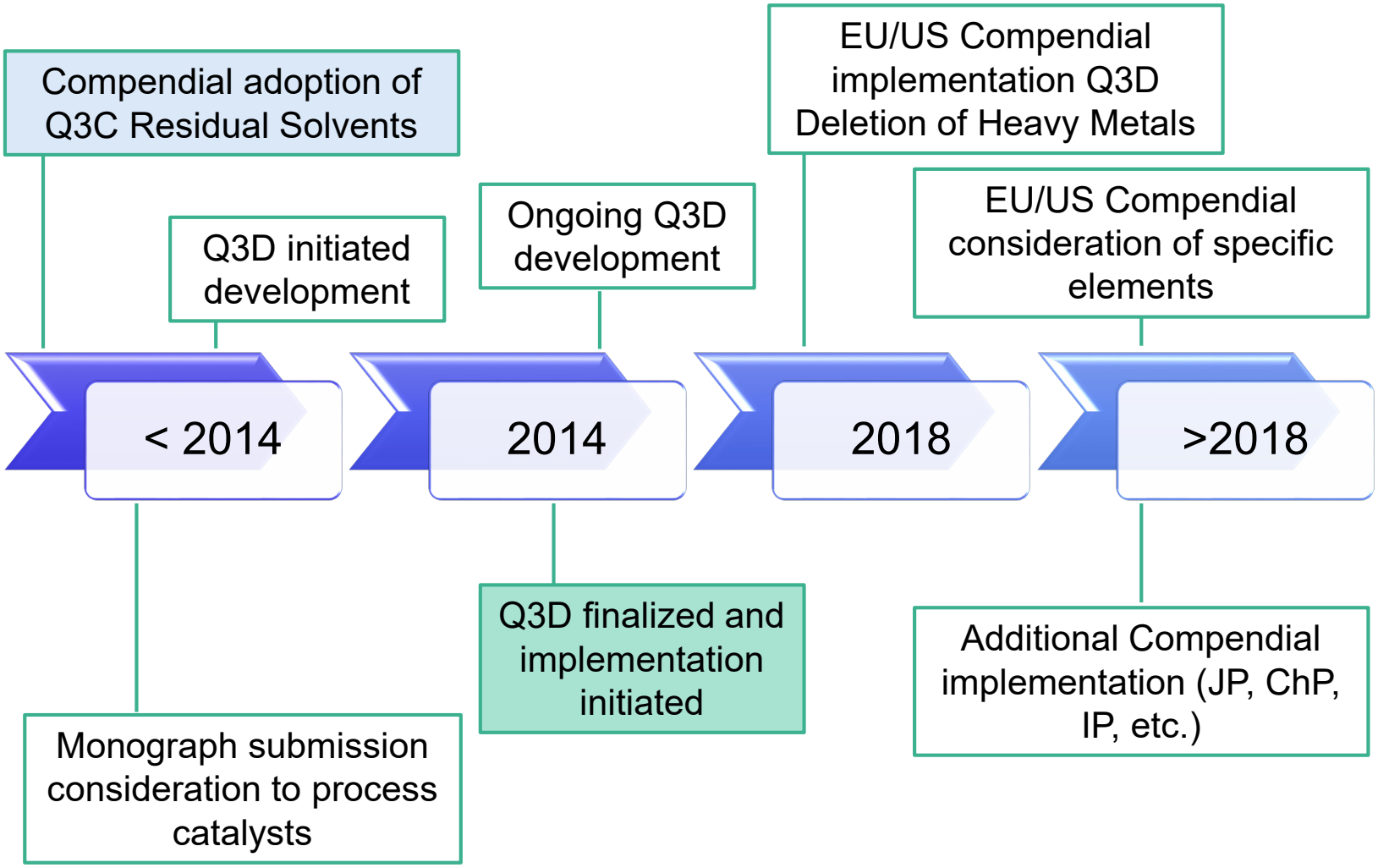
ICH **Knowledge** and **Safety** Based Guidelines

1. Global Regulatory, Pharmacopeia, and Industry collaboration and harmonization
2. Focuses resources where risk is identified
3. Safety based limits reduce conflicts across multiple individual applications
4. Flexible methodology reduce conflicts across multiple individual applications
5. Simplify Pharmacopeial content, resources and supports further harmonization efforts
6. Supports innovation through flexibility



Development

Development



Development

2015-2018: ICH Q3D Learning Curve

1. Theory becomes Application
   - Industry risk assessments and control strategy confirmation
   - Regulatory compliance confirmation and change control

2. Managing the learning curve and secondary impact across market portfolio
   - Deleting Heavy Metals
   - Retaining specified elements

Opportunities

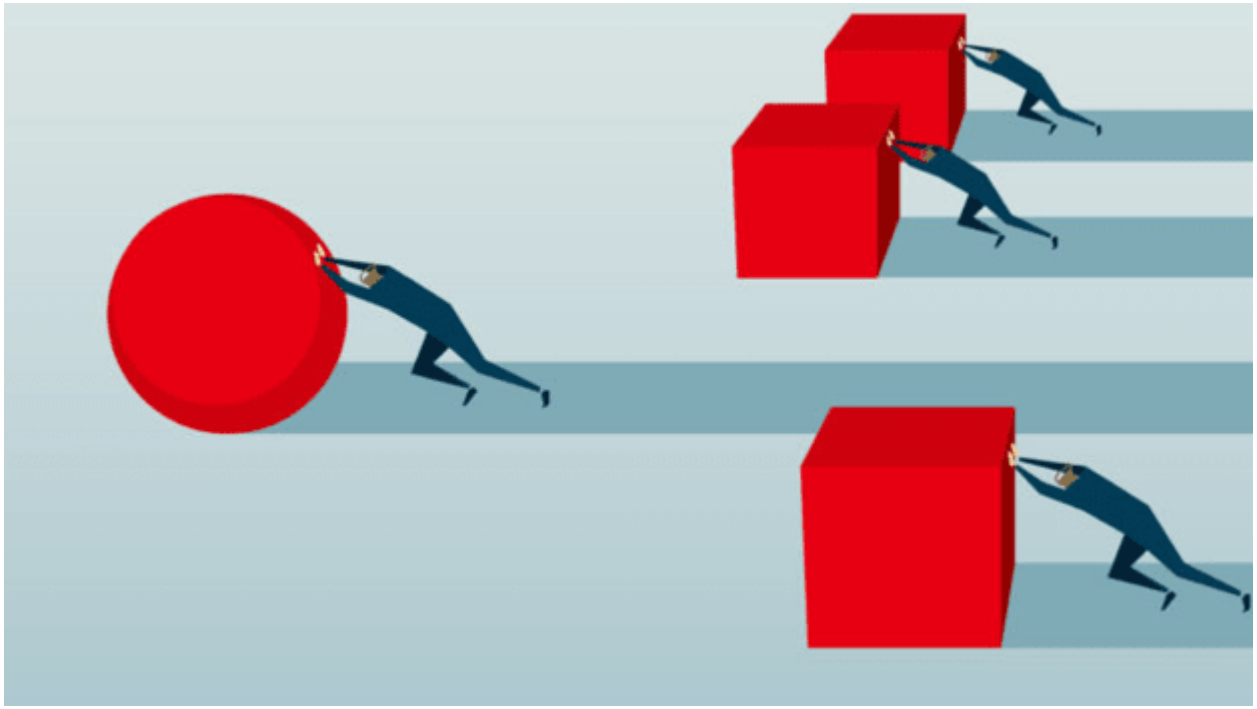
Opportunities

1. Simplify ongoing alignment with ICH Q3D
   - Direct reference to ICH Q3D content (Ex. Ph. Eur. 5.20 Elemental Impurities)
     - Define revision implementation timelines
     - Minor revisions – Suggest 6 months
     - Major revisions – To be determined base on unique attributes

2. Maximize benefits of Knowledge and Safety based expectations
   - Simplify monograph and chapter content (Ex. ICH Q3C Residual Solvent applications)
   - Define a universal standard where retaining an element is justified
   - Where justified, retained elements should not be limited to a single method and limits should refer to Q3D safety expectations

3. Additional Pharmacopeial implementation
   - Concurrent Heavy Metals and specific element transition
   - Retain element specific general chapters as resource
   - Share knowledge with Regulatory and Pharmacopeial Agencies internationally as they adopt ICH Q3D

Challenges



Challenges

1. Define a universal standard where retaining an element is justified
   - "Other Element" limit in a material monograph is not a product Permitted Daily Exposure limit
2. Avoid conflicts with ICH Q3D
   - Reinterpretation
   - Retaining or adding rigid requirements (methods/limits)
3. Managing changes and the compounded impact to multi-national filings
   - Ex. Change specified element
     - Assess Product(s) control strategy
     - Method development increases implementation time
     - Where risk is identified, update control strategy
     - (These are not the only compendial changes occurring)

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Thank You