

Elemental Impurities – Lifecycle Management

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*PQRI/USP Elemental
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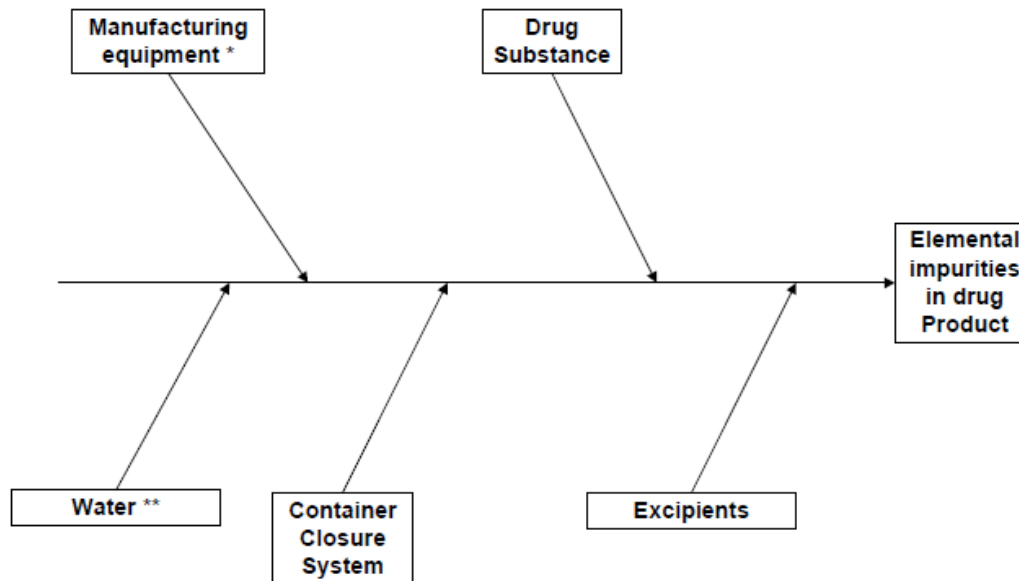
Lifecycle Management Objectives

- The Lifecycle approach is to ensure ongoing compliance to Elemental Impurity requirements.
- An understanding of the product and/or process changes which have the potential to change the Elemental Impurity content of the final product and therefore may require a re-evaluation of the overall risk assessment and control strategy to ensure ongoing compliance to Elemental Impurity requirements

Lifecycle Management

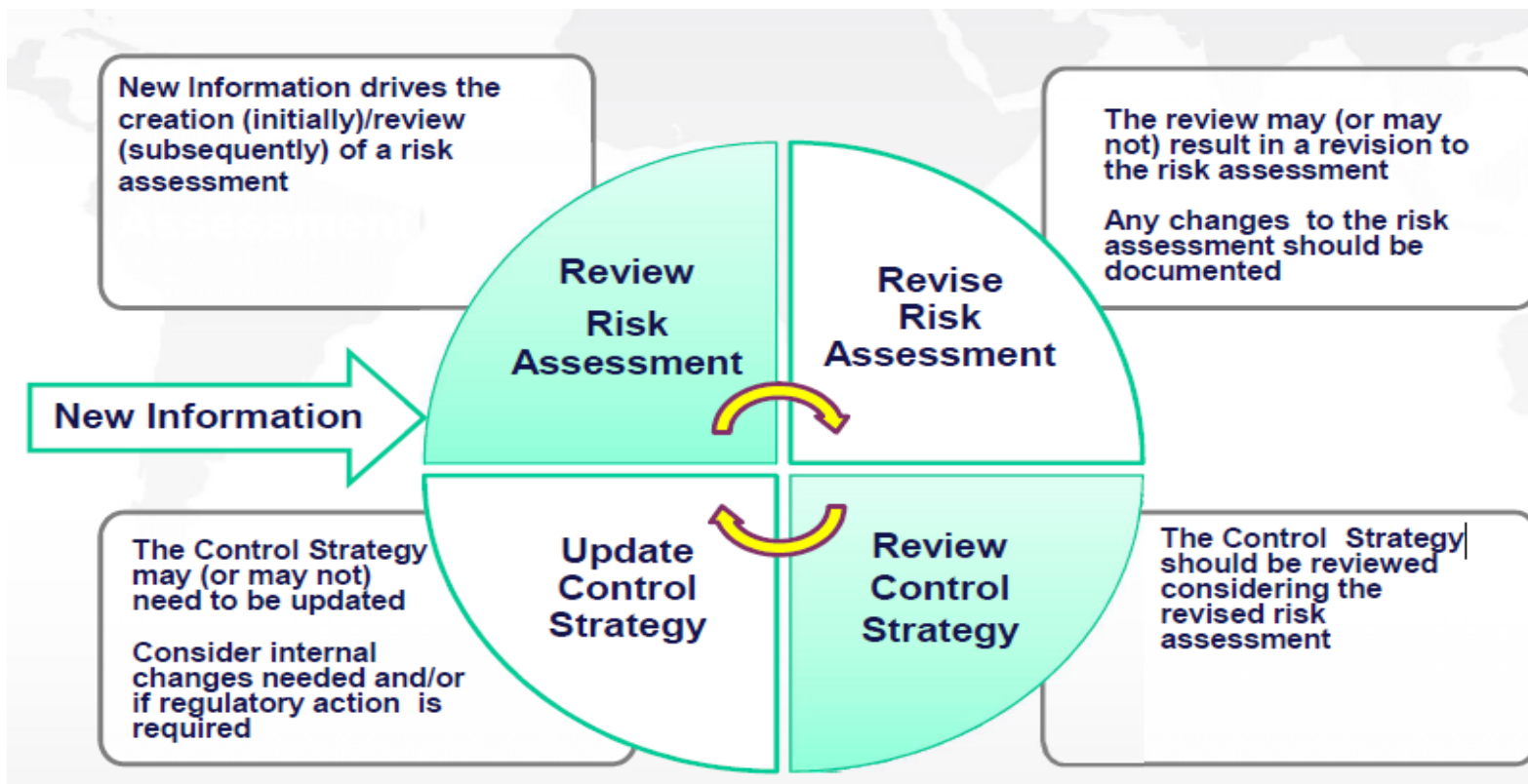
- Essential to Lifecycle management is an understanding of how changes in the product/process and/or components may impact the Elemental Impurity risk assessment and the need for a control strategy on the drug product.
- Changes Potentially Impacting Elemental Impurities:

Risk Assessment Fishbone Diagram



Lifecycle Management

Lifecycle Approach



Graphic from ICH Q3D Training Module 6 Control of Elemental Impurities

Possible Changes to a Drug Product

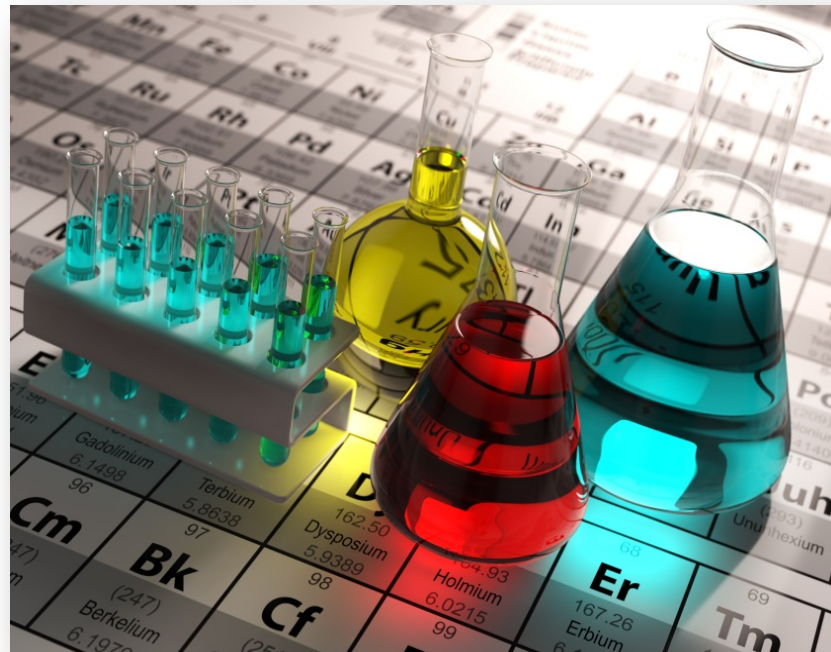
- Examples of changes which may lead to reviews of the original risk assessment and control strategy are:
 - Synthetic routes
 - Excipient suppliers
 - API suppliers
 - Materials
 - Processing equipment
 - Container closure
 - Water supply

Summary/Conclusion

- Elemental Impurity Lifecycle Management ensures that a change to the product and/or process have been properly evaluated for the potential to change the elemental impurity content of the final product.
- Changes made to any of the 5 components of the Drug Product (Manufacturing Equipment, Water Systems, Container closure, API and Excipient) require review and potentially revision of the risk assessment and control strategy.
- Risk Management principles and Global Change Management processes are key to ensuring ongoing compliance to Elemental Impurities.

References

- ICH Q3D Training Module 6
- ICH Q3D Elemental Impurities - Frequently Asked Question Number 18.



Questions

