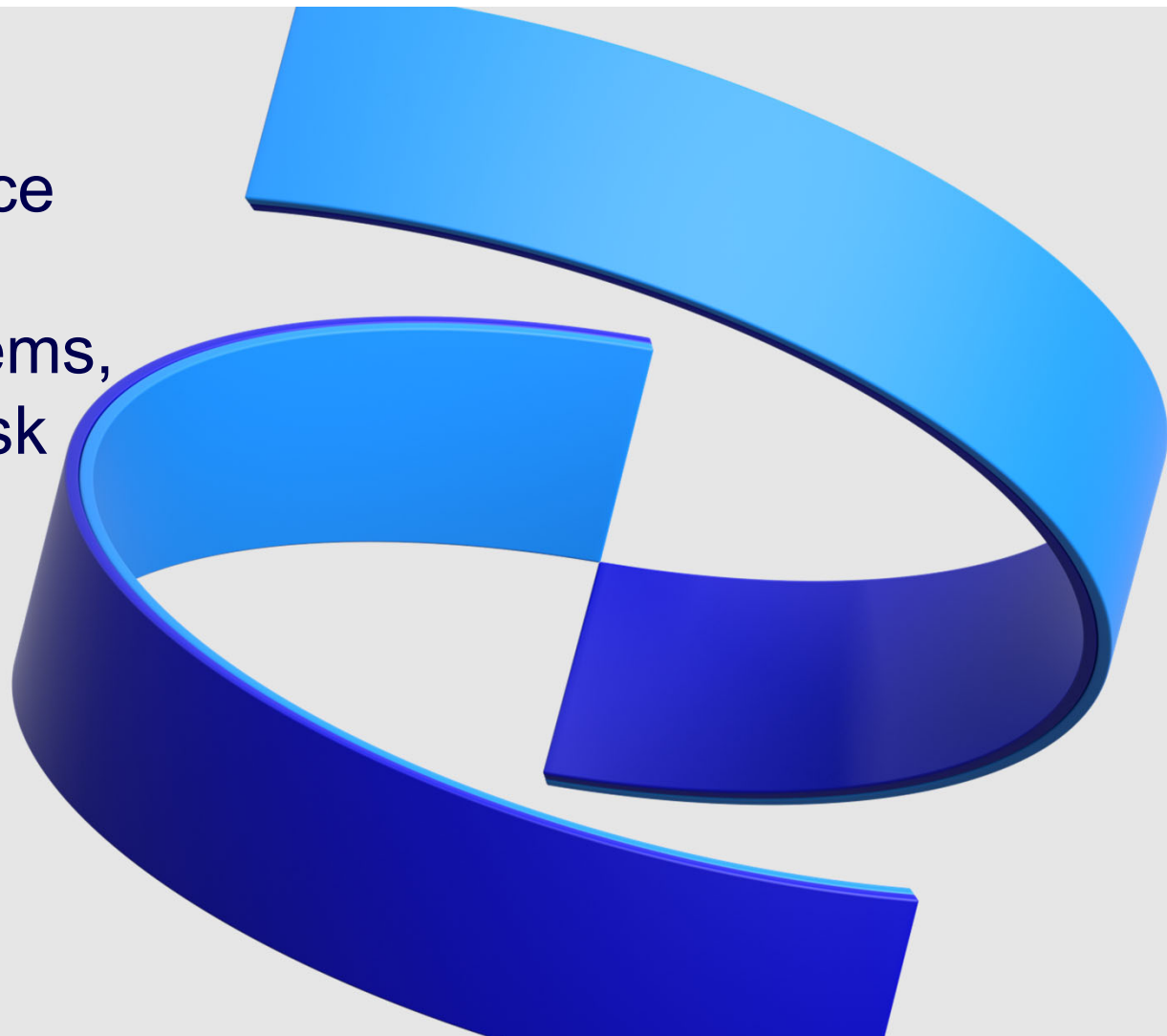


# Innovative Drug & Device Technologies & Their Impact on Quality Systems, Control Strategies & Risk Management

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Associate Research Fellow  
25 Jan 2023



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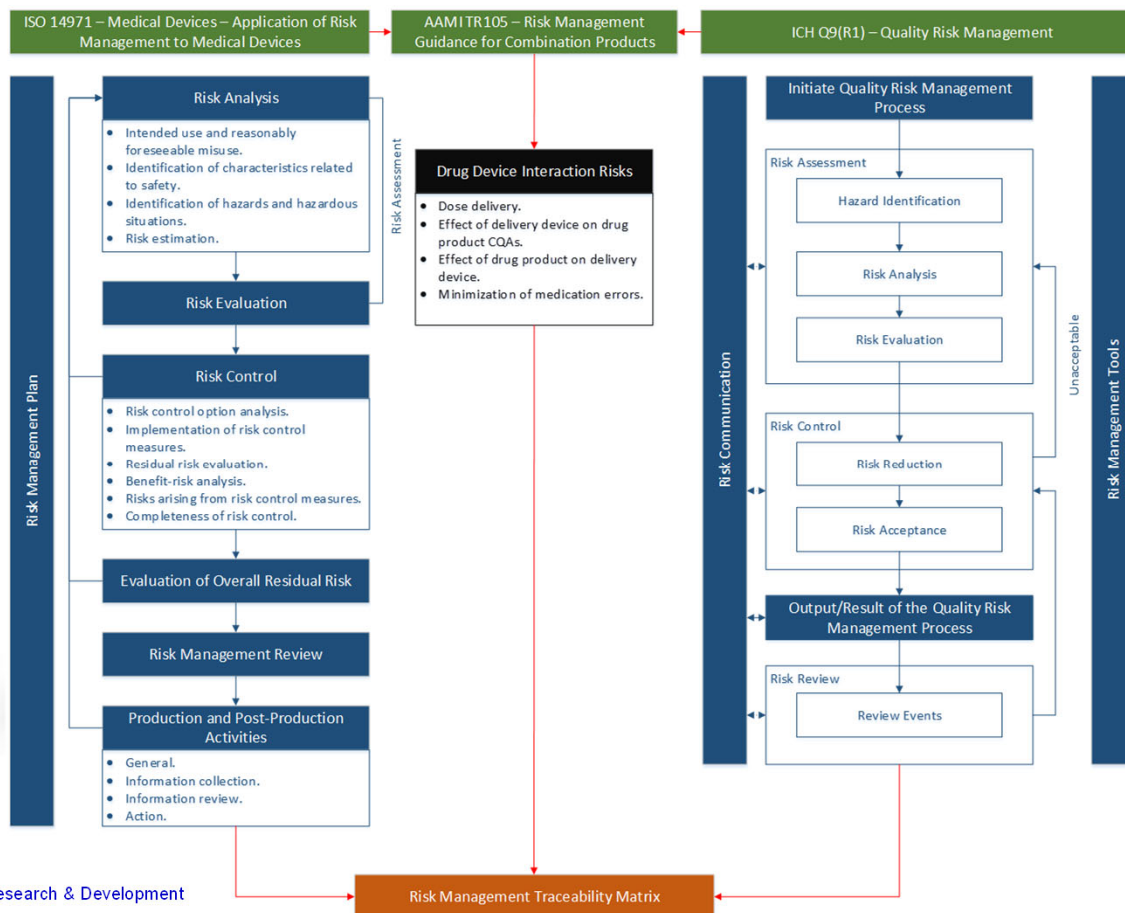
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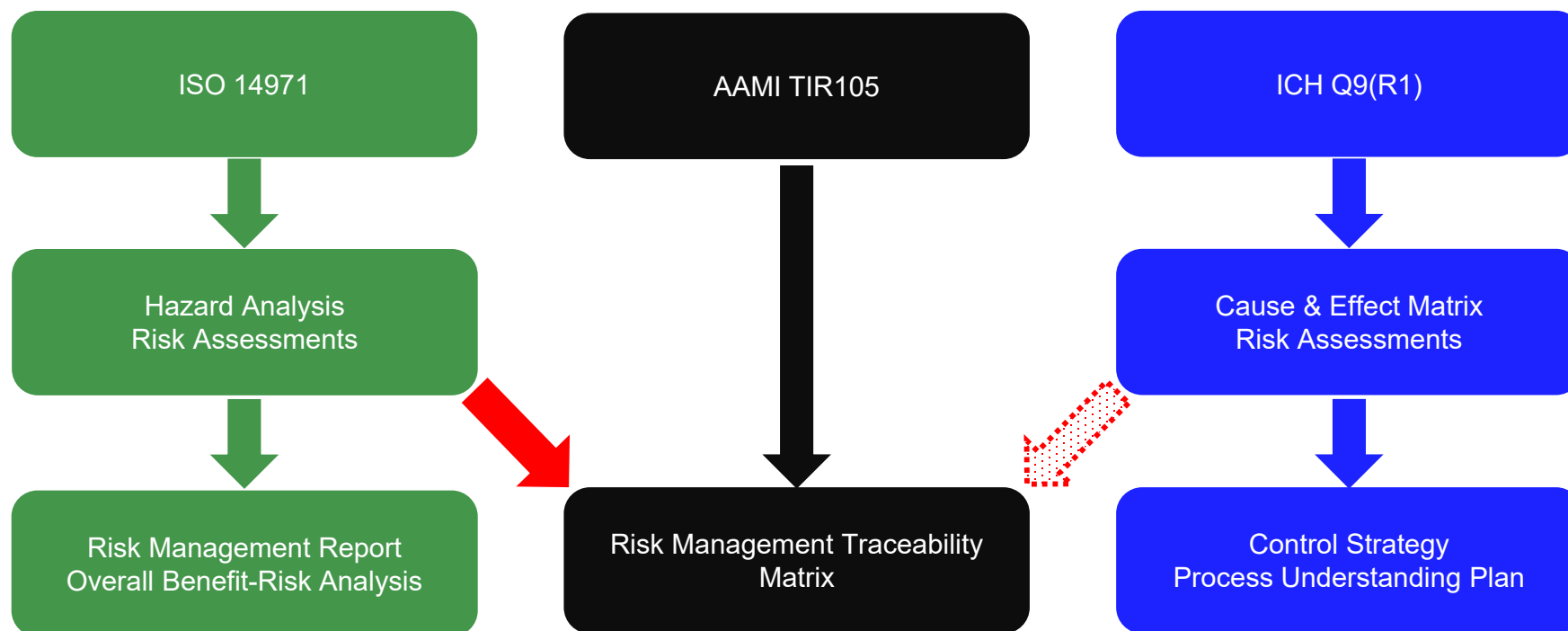
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# AAMI TIR105:2020 Approach



## Current Reality





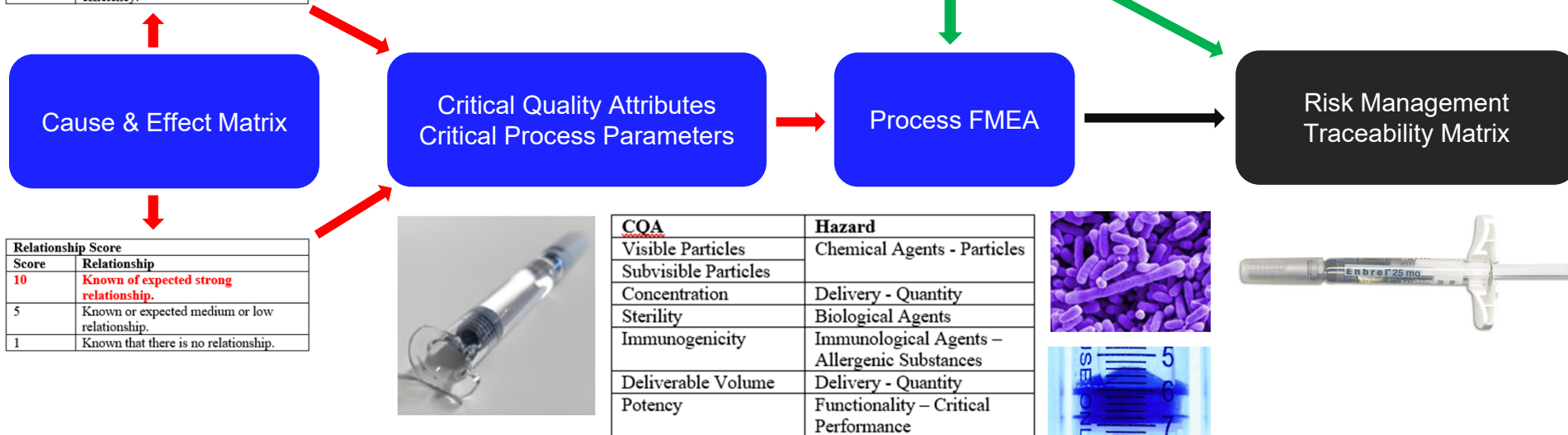
# Linking Drug & Device Risk Assessments

Attribute Score	
Score	Description
10	Established or expect a direct impact on safety and/or efficacy of product.
7	Moderate or indirect impact on safety and/or efficacy. Direct impact on efficiency.
5	Low or unlikely impact to product safety and/or efficacy. Moderate or indirect impact efficiency.
1	No impact to product safety and/or efficacy. Low or unlikely to impact efficiency.

Common terms	Possible description
Catastrophic / Fatal	Results in death
Critical	Results in permanent impairment or irreversible injury
Serious / Major	Results in injury or impairment requiring medical or surgical intervention
Minor	Results in temporary injury or impairment not requiring medical or surgical intervention
Negligible	Results in inconvenience or temporary discomfort

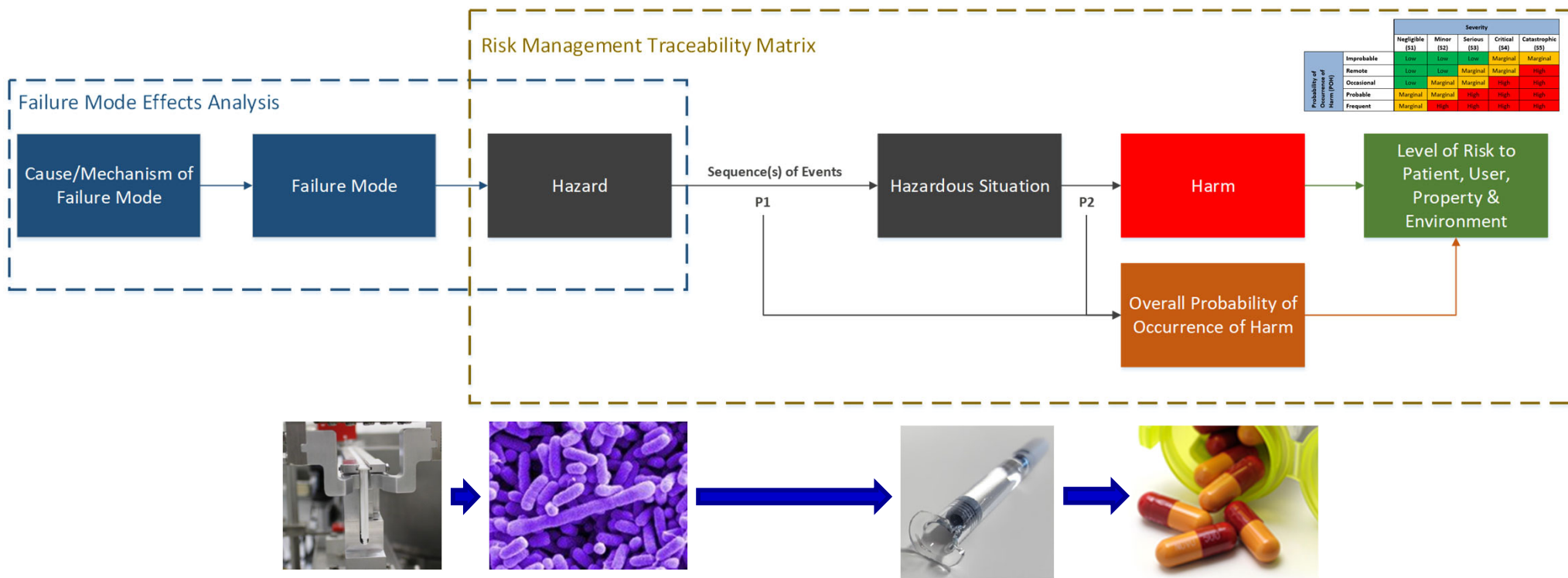
ISO 14971:2019 – Medical Devices – Application of Risk Management to Medical Devices

Hazard	Hazardous Situation	Harm	Severity of Harm
<b>Chemical &amp; Biological Hazards</b>			
Biological Agents (Bacteria, Viruses, Fungi & Parasites)	Administration of biological agent into the patient.	Death. Systemic infection (sepsis), permanent impairment or life-threatening/irreversible injury. Localized infection, abscess, systemic effects, requiring medical/surgical intervention. Localized infection, not requiring medical intervention.	Catastrophic (S5) Critical (S4) Serious (S3) Minor (S2)

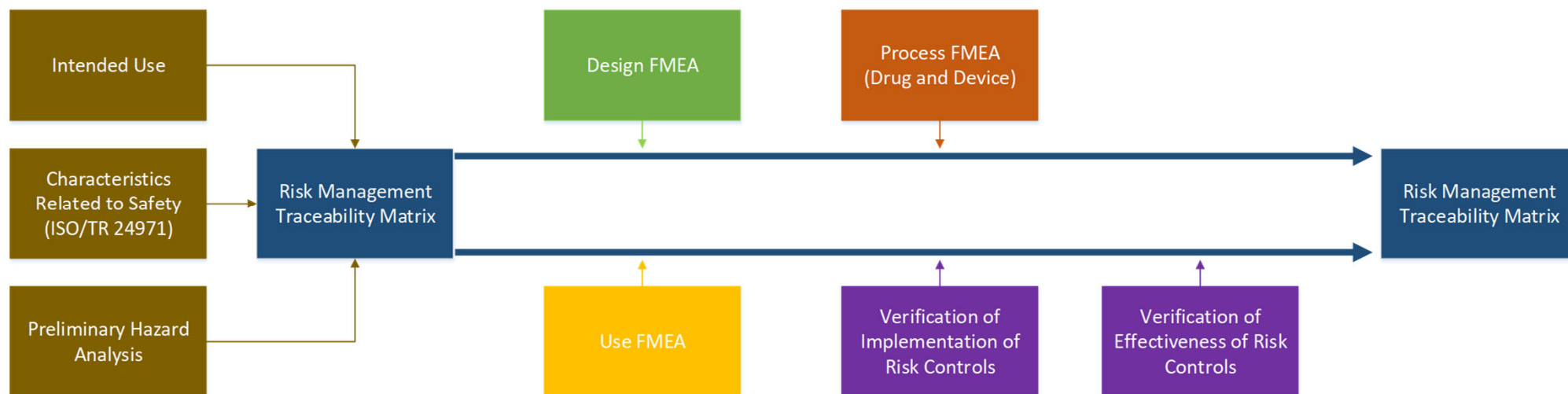




# Failure Mode Analysis & Risk Analysis Relationship



# Risk Management Traceability Matrix





# Drug Agnostic Risk Assessments



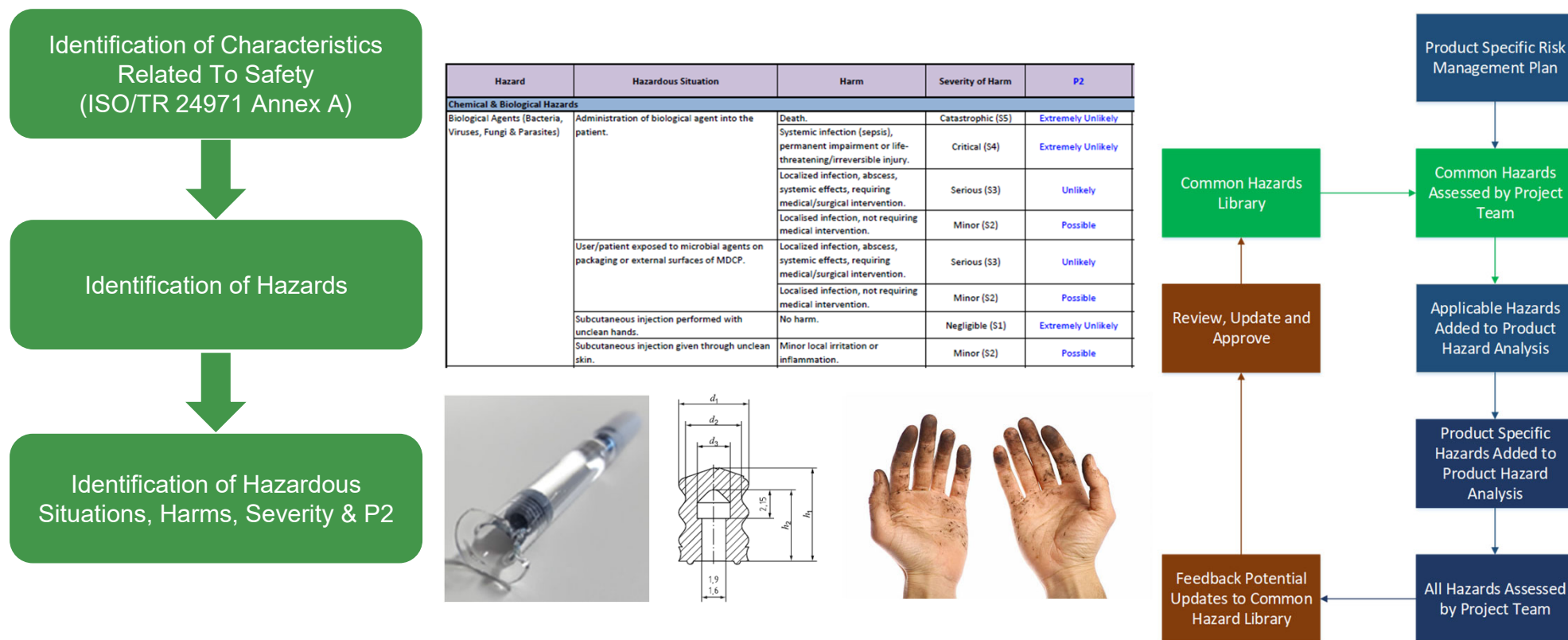
- Four different risk management files.
- Risk of inconsistencies between common hazards.
- Burden on time.



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# Drug Agnostic Risk Assessments – Common Hazards





## Conclusions

- AAMI TIR105:2020 provides a good architecture for assessing combination product risk and is device independent.
- Failure of a drug product to meet CQA requirements can be assessed in an ISO 14971 context.
- Approach results in holistic combination product risk assessments with little extra work.
- Drug agnostic risk assessments save time and drive consistency when same platform device utilized over multiple drug products.

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# Thanks

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Business Group Name Here

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# Thank You



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