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# Implementing Quality Risk Management at Amgen

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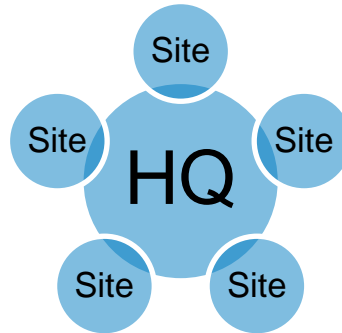
Rebecca Spohn

Risk Management Sr. Manager

# Quality Risk Management is a key element in Amgen's Quality System

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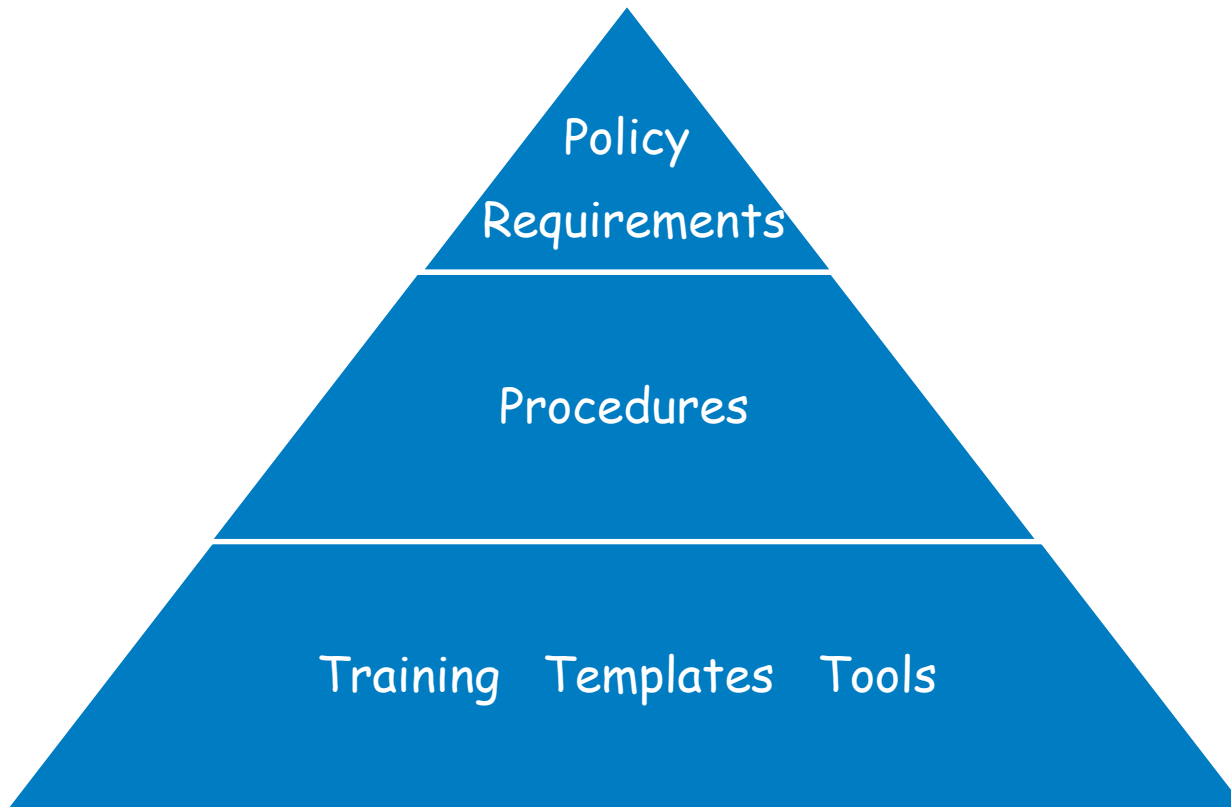
- Quality Risk Management is an established Quality System Process
- QRM program is managed globally to ensure consistent, complete implementation that meets global objectives



- Prioritization of risk management activities is managed locally, under the level of leadership accountable for the risk

# What are the elements of a formal QRM program?

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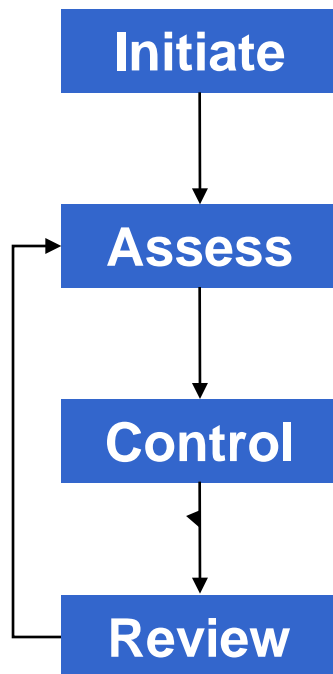


**Number of tiers may vary, depending on level of maturity and formality**

# QRM Policy and Requirements



## The Q9 Process



## Policy and Requirements documents provide program objectives

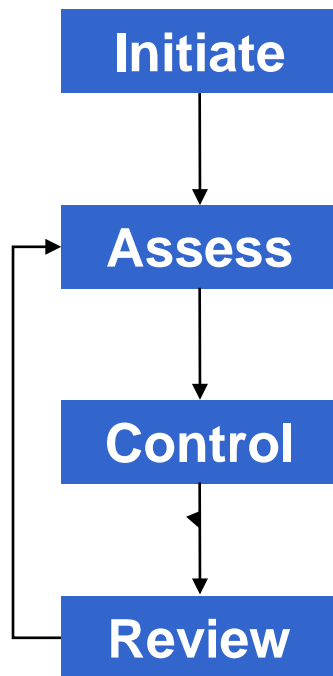
- ❖ QRM activities should be well-planned and properly resource.
- ❖ Risks will be identified, analyzed & evaluated against thresholds to determine if additional actions are needed.
- ❖ Action will be taken to reduce risks with scores above thresholds to acceptable levels. Action will be tracked.
- ❖ Risks will be reviewed at defined intervals or upon defined events.

**A Quality Risk Management policy structured in accordance with ICH Q9 will satisfy most risk management needs**

# QRM Procedures



## The Q9 Process



## Procedures establish process flow

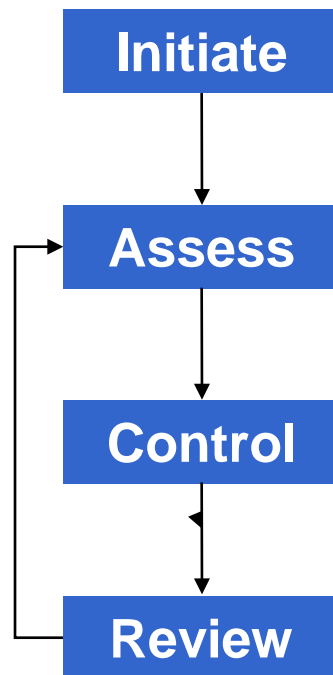
- ❖ Risk assessment prerequisites and preparation activities are delineated. Roles & responsibilities are included.
- ❖ Risk rating guidance provided. Results documented in a risk assessment summary report or other controlled document.
- ❖ Guidance for setting thresholds provided. Actions will be tracked.
- ❖ Frequency and/or triggers for review are defined. Risks may be reviewed at development gates, annual product reviews, or other management reviews.

**Procedures explain how policy objectives and requirements will be met**

# QRM Training, Templates and Tools



## The Q9 Process

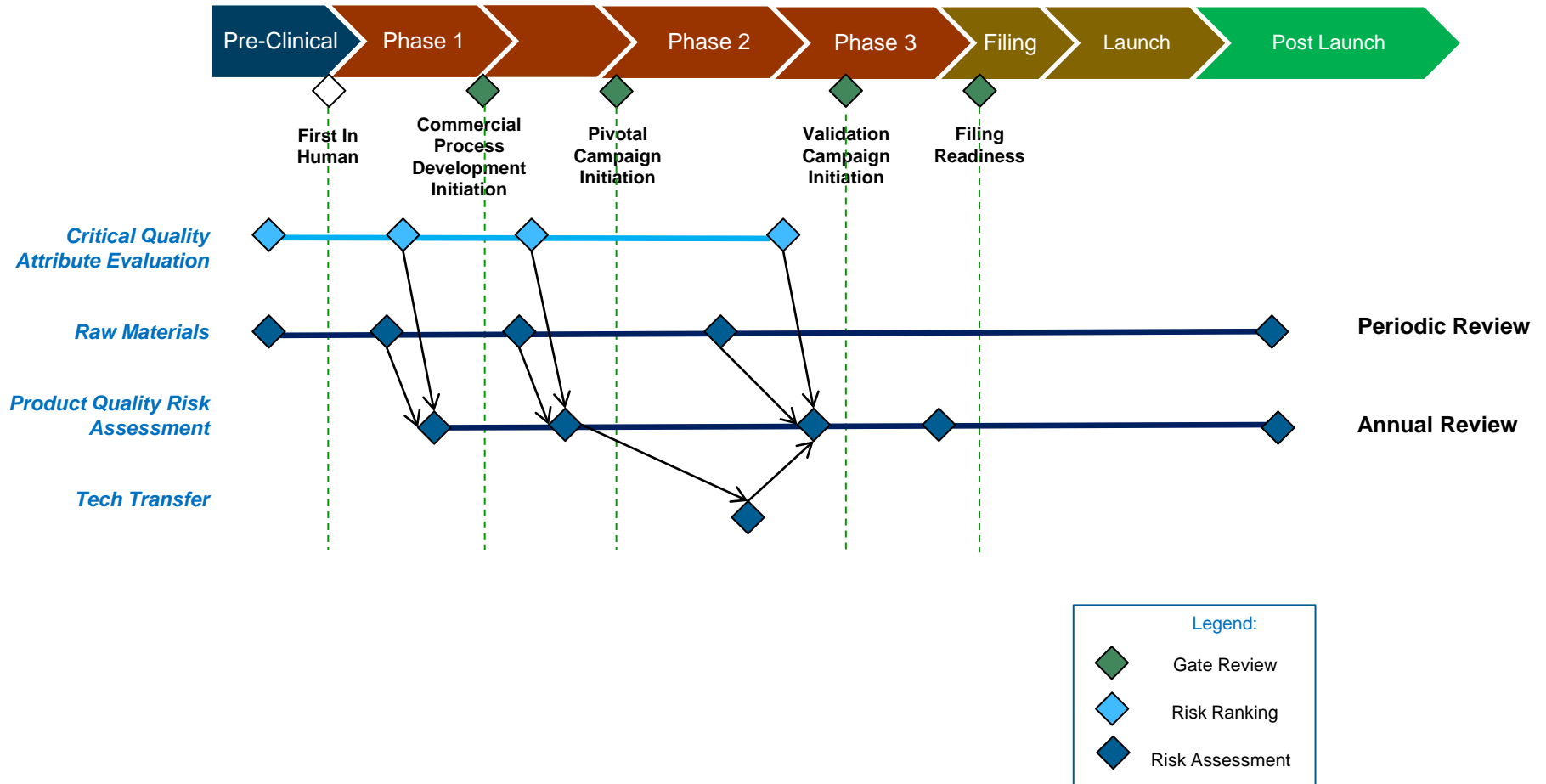


## Training, Templates and Tools provide consistency and completeness

- ❖ Plan templates may be provided. Stakeholders trained on how to prepare for an assessment.
- ❖ Templates for risk assessment worksheets and reports. Software tool may be provided.
- ❖ Tracking risk controls for licensed products may require systems such as CAPA, Change Control or Work Order Systems
- ❖ Train stakeholders on how to use risk reviews to keep risk assessments living

**Training, templates and tools provide the detailed elements to deliver on requirements.**

# Product Quality Risk Assessments are conducted at key points in the Product Development lifecycle



# Thank you

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