

# APPLIED PRODUCT RISK ASSESSMENT

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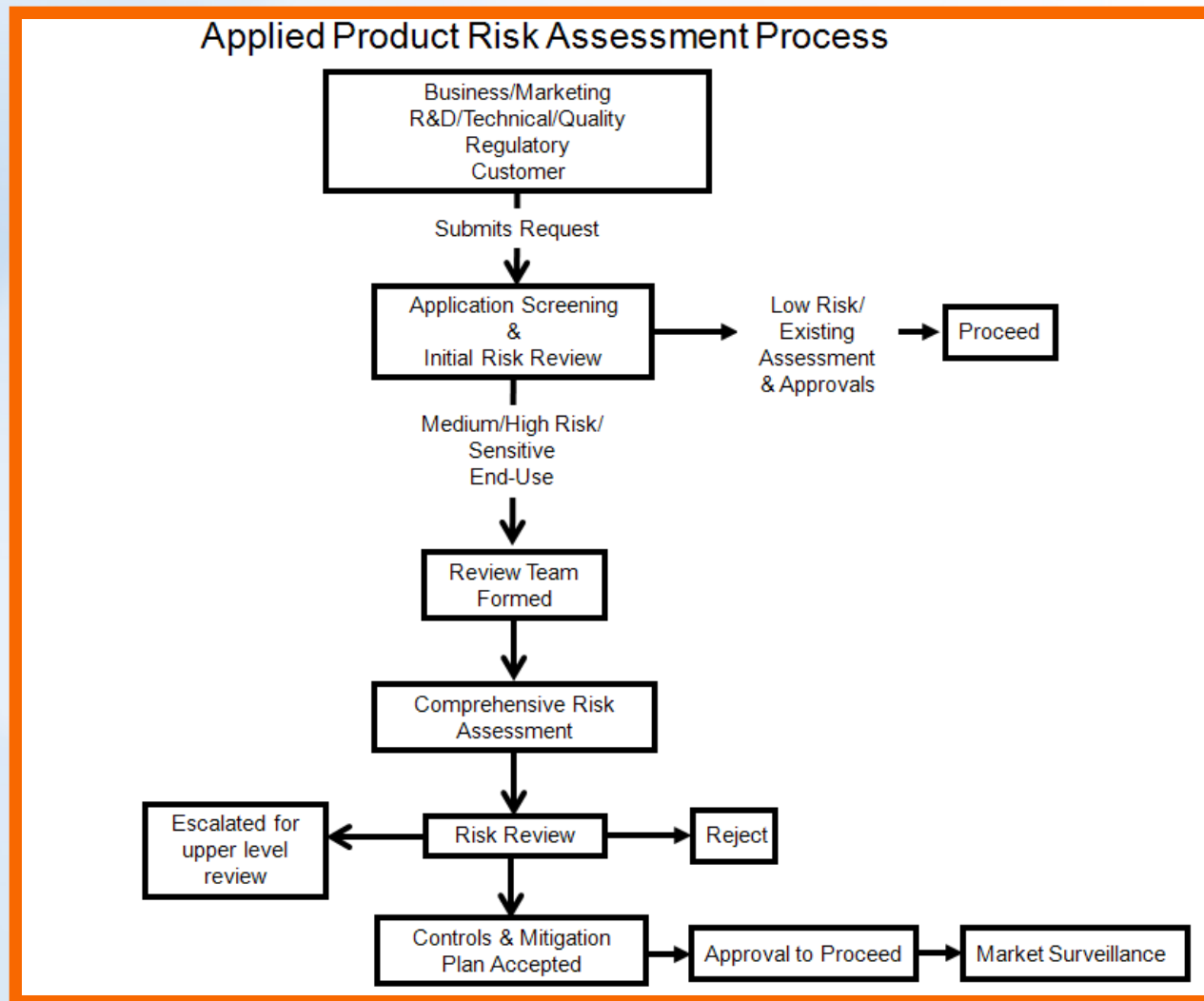
# Outline

- ▶ Introduction- What is Applied Product Risk Assessment?
- ▶ Workflow Process Overview
  - ▶ Trigger / Request
  - ▶ Application Screening/Initial Risk Review
  - ▶ Review Team
  - ▶ Comprehensive Risk Assessment
  - ▶ Level of Risk and Approval
  - ▶ Control & Mitigation Plan
  - ▶ Market Surveillance
- ▶ Summary

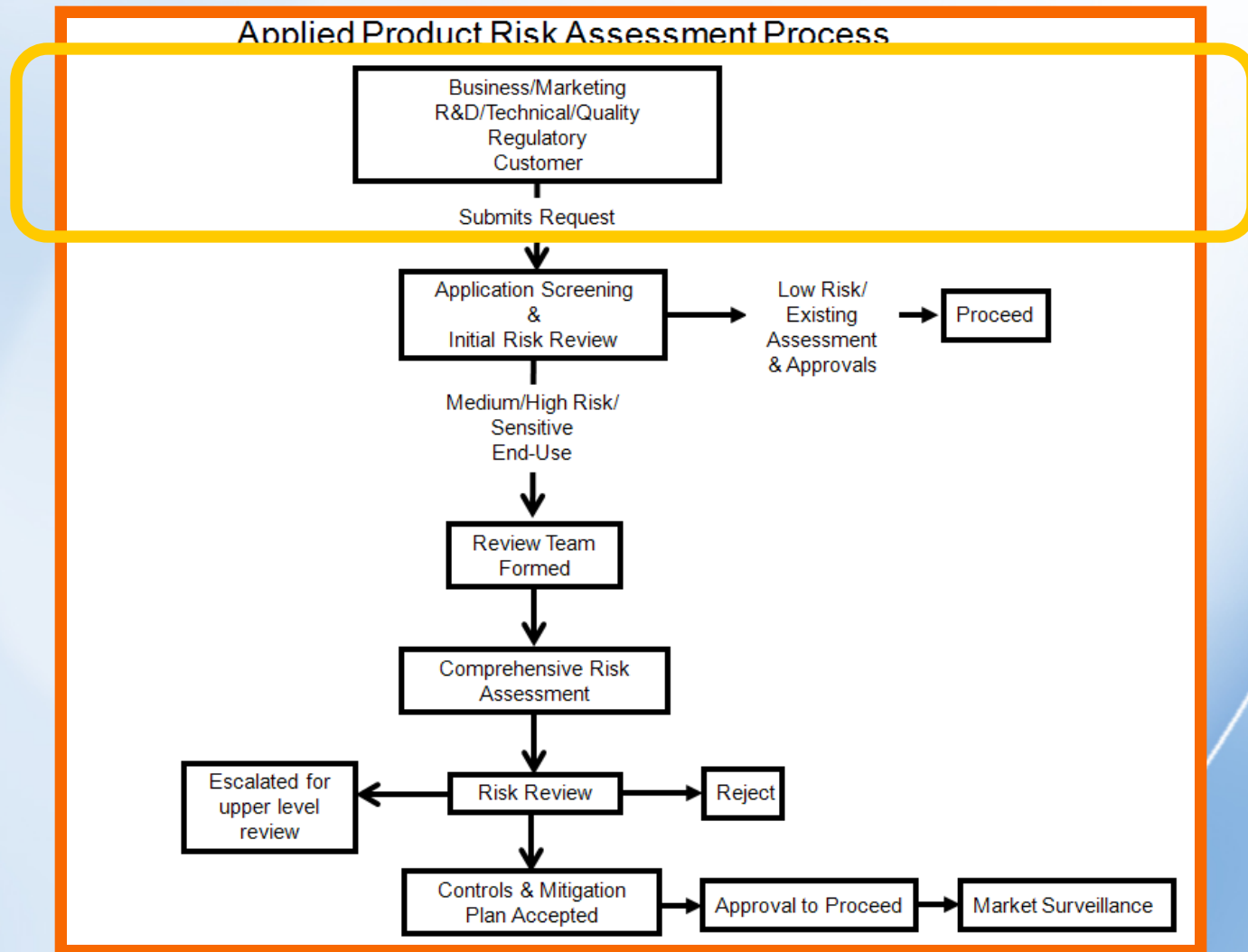
# Introduction- What is Applied Product Risk Assessment?

- ▶ Global risk management process
- ▶ Identify and manage product-related risk
  - raw materials, manufacturing, handling, distributing, sale and the end-use of products.
- ▶ Framework best practices and industry benchmarks
- ▶ Governing guiding principle & strategy

# ► Workflow Process Overview



# ► Trigger / Request



## ▶ Trigger / Request

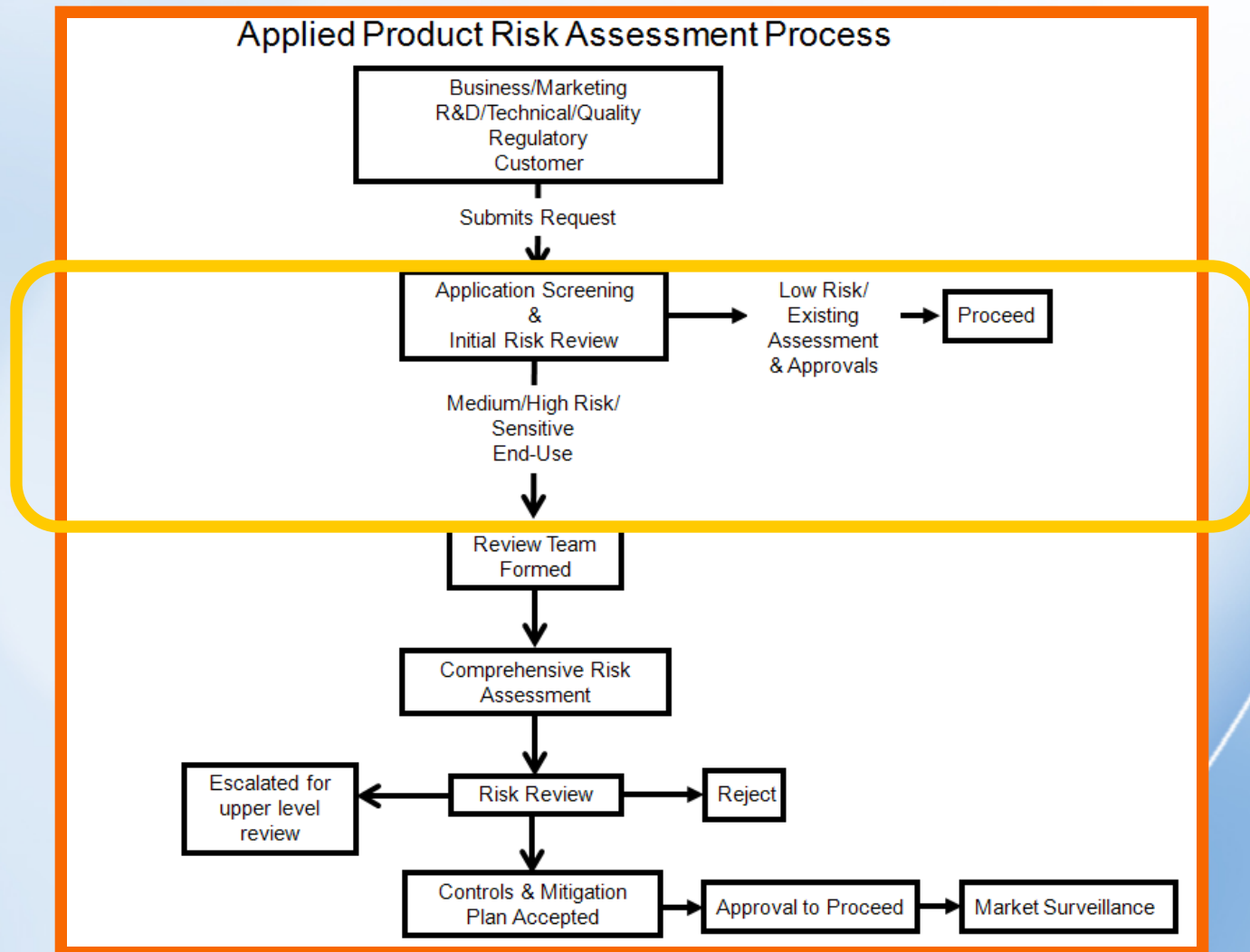
Electronic Submission



### Trigger or Reason for Request:

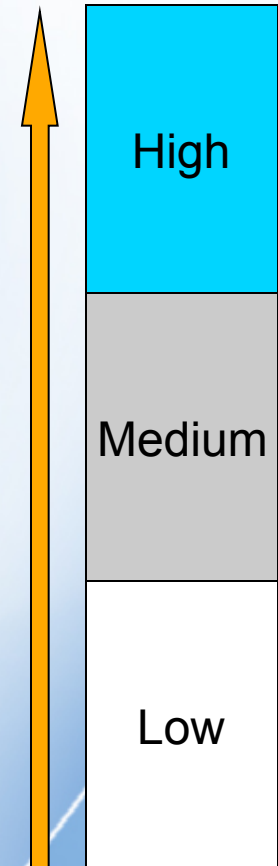
- ▶ New products
- ▶ New end-uses
- ▶ New projects
- ▶ Significant product changes
- ▶ Raw material changes
- ▶ Processing changes
- ▶ Supplier changes
- ▶ Safety/Toxicology
- ▶ Regulatory

# ▶ Application Screening/Initial Risk Review



# ▶ Application Screening/Initial Risk Review

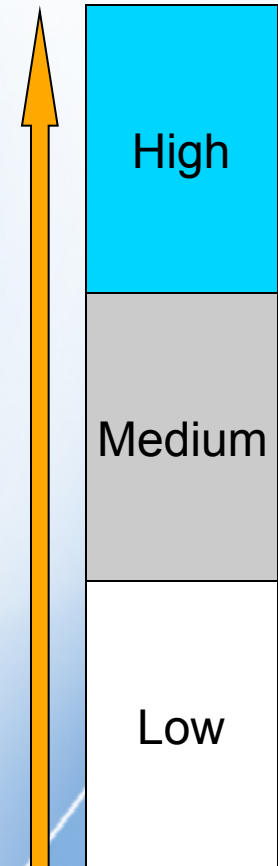
- ▶ New Product/Application Screening
- ▶ Risk Level (Low – Medium – High)
- ▶ Exposure
- ▶ Hazard
- ▶ Regulatory
- ▶ Legal
- ▶ Quality
- ▶ Manufacturing
- ▶ Data Review



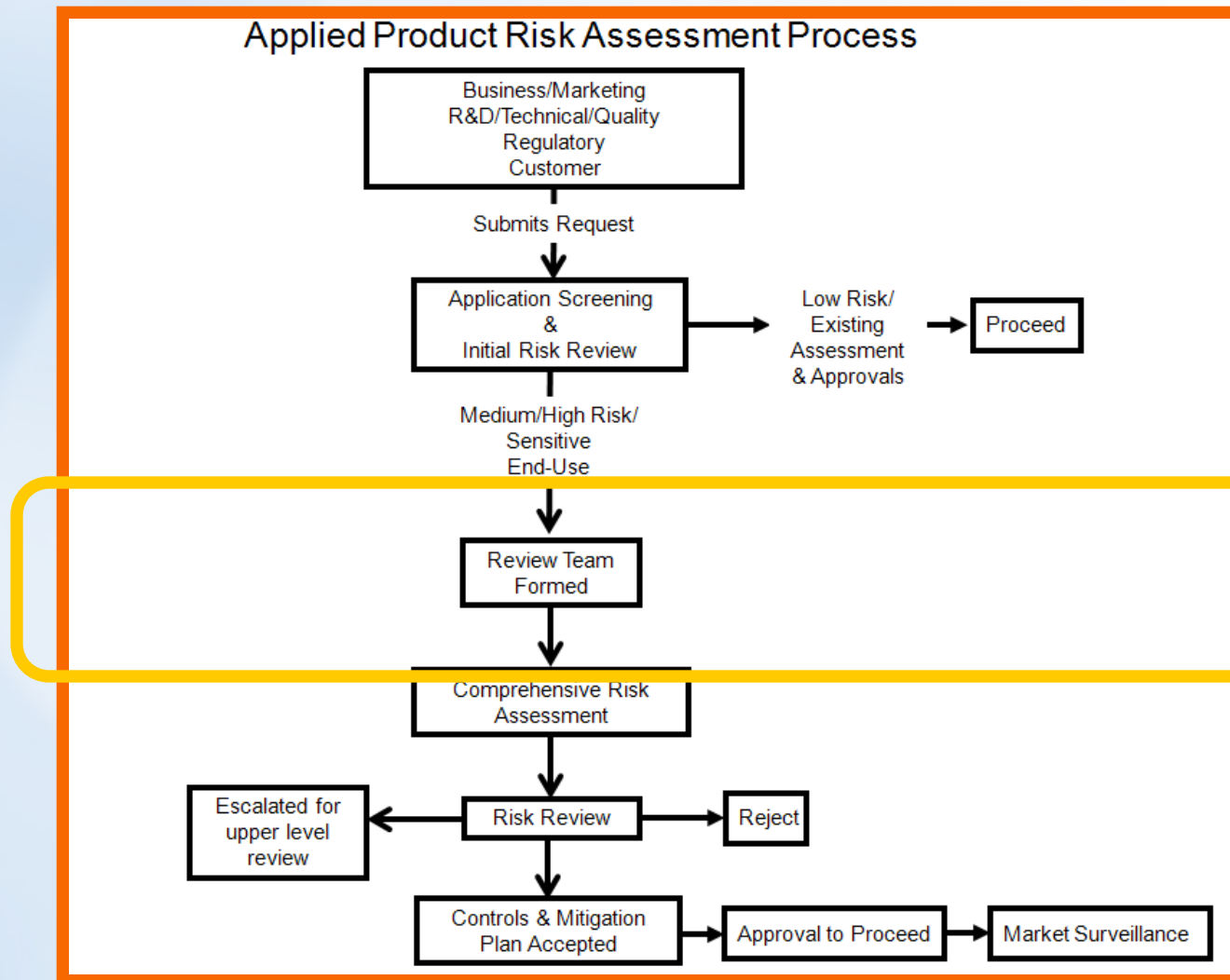


# ▶ Application Screening/Initial Risk Review

- ▶ Risk Assessment
- ▶ Escalated Management Review and Approval
- ▶ Novel projects and Ideation
  - funnel potential projects into the next level of stage gate or product development phase



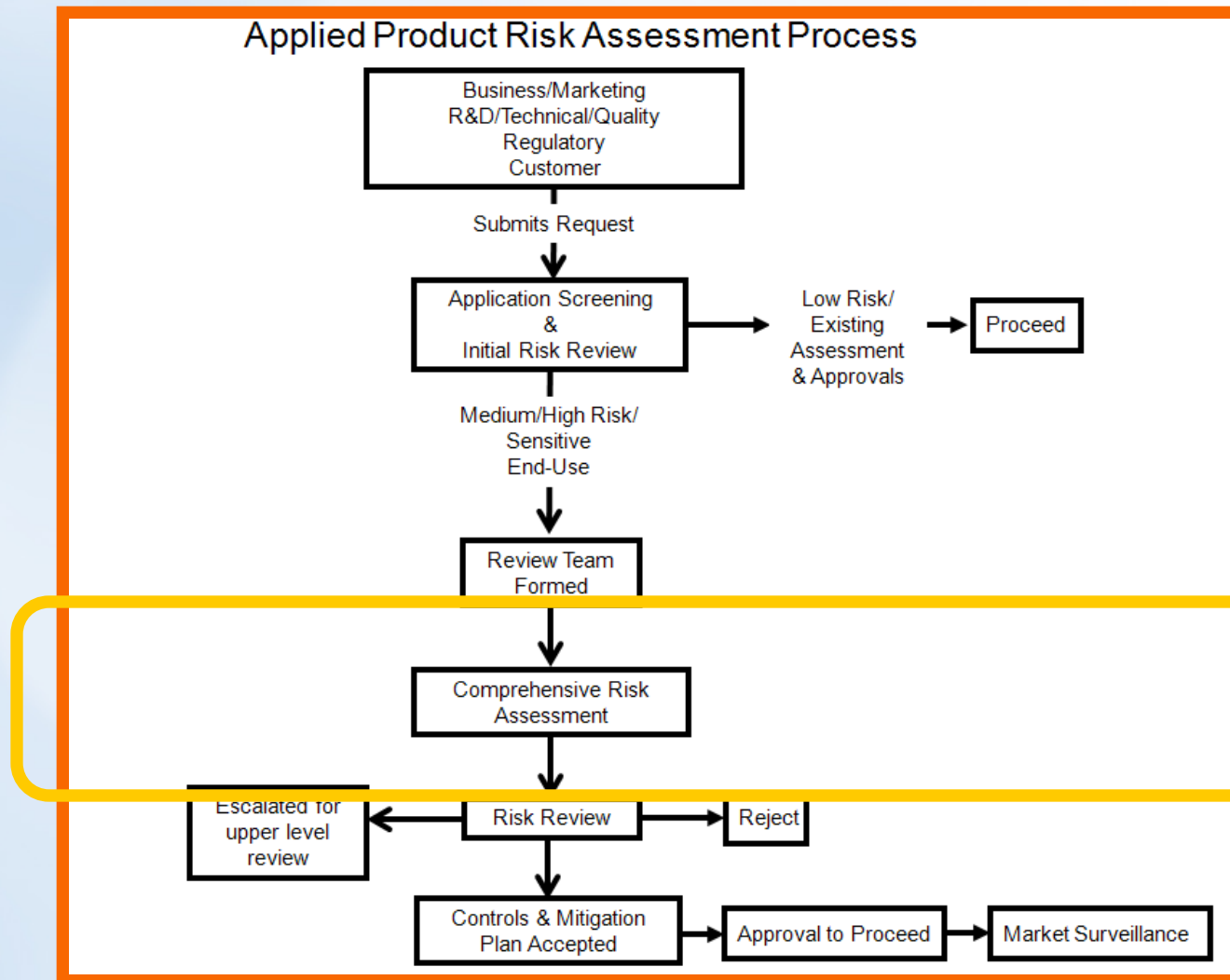
# ► Review Team



# ▶ Review Team

- ▶ Cross-functional departmental participation
- ▶ Coordination of Experts
  - ▶ Product Stewardship/Toxicology
  - ▶ Legal
  - ▶ Product Development and R&D
  - ▶ Sales
  - ▶ Marketing
  - ▶ Manufacturing
  - ▶ Quality
  - ▶ External Resources

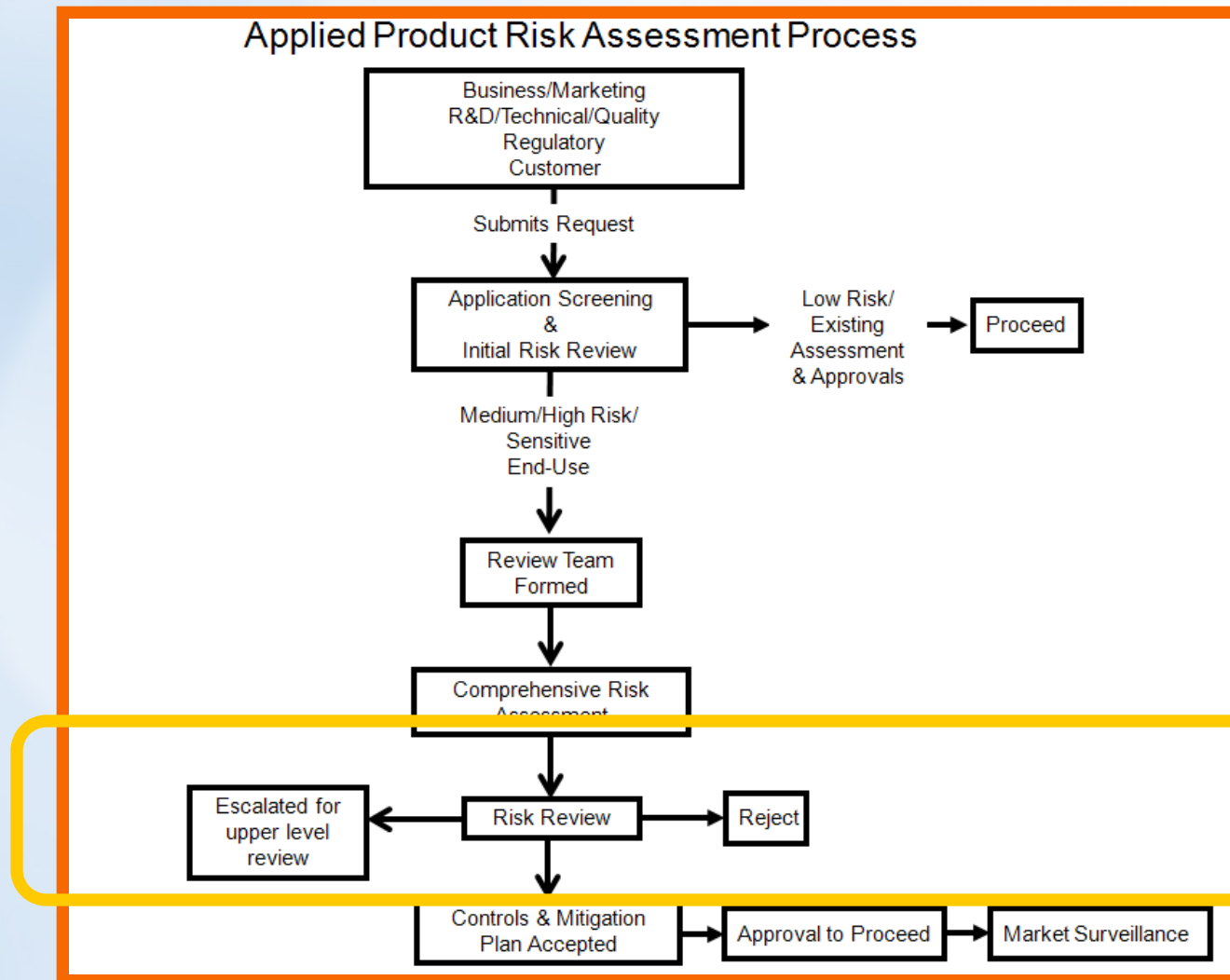
# ► Comprehensive Risk Assessment



# ▶ Comprehensive Risk Assessment

- ▶ Product Stewardship/Toxicological Review and Testing
- ▶ Legal Review
- ▶ Regulatory Review
- ▶ Claims Substantiation Review
- ▶ R&D Review & Testing
- ▶ Quality Review
- ▶ Manufacturing Review
- ▶ External Third Party Review
- ▶ Mitigation Plan

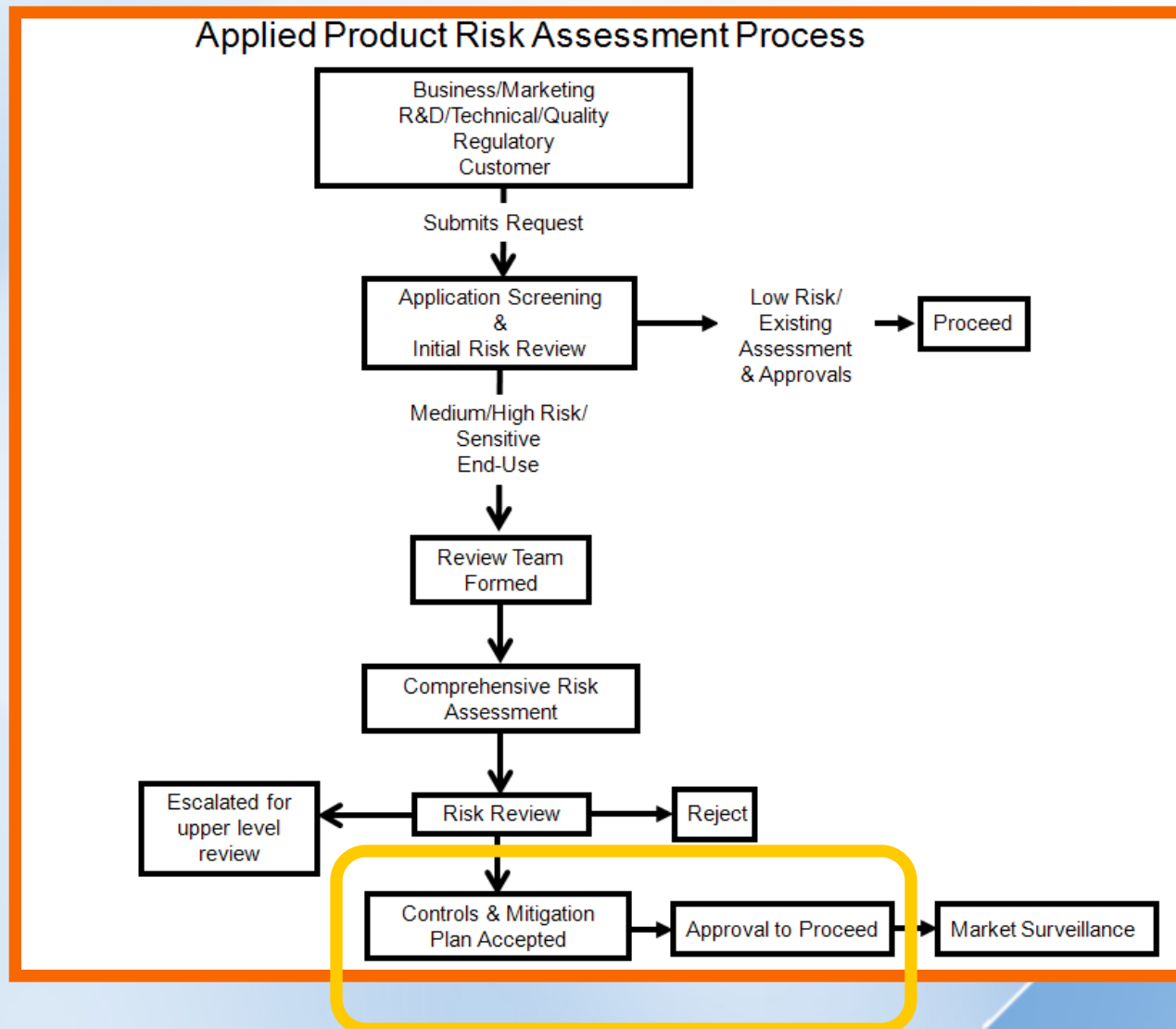
# ► Level of Risk and Approval



## ▶ Level of Risk and Approval

- ▶ Review and evaluation by review team
- ▶ Risk measure controls
- ▶ Updated risk score
- ▶ Escalated Management Review and Approval
- ▶ Reject or Approve

# ► Controls and Risk Measures





## ▶ Controls and Risk Measures

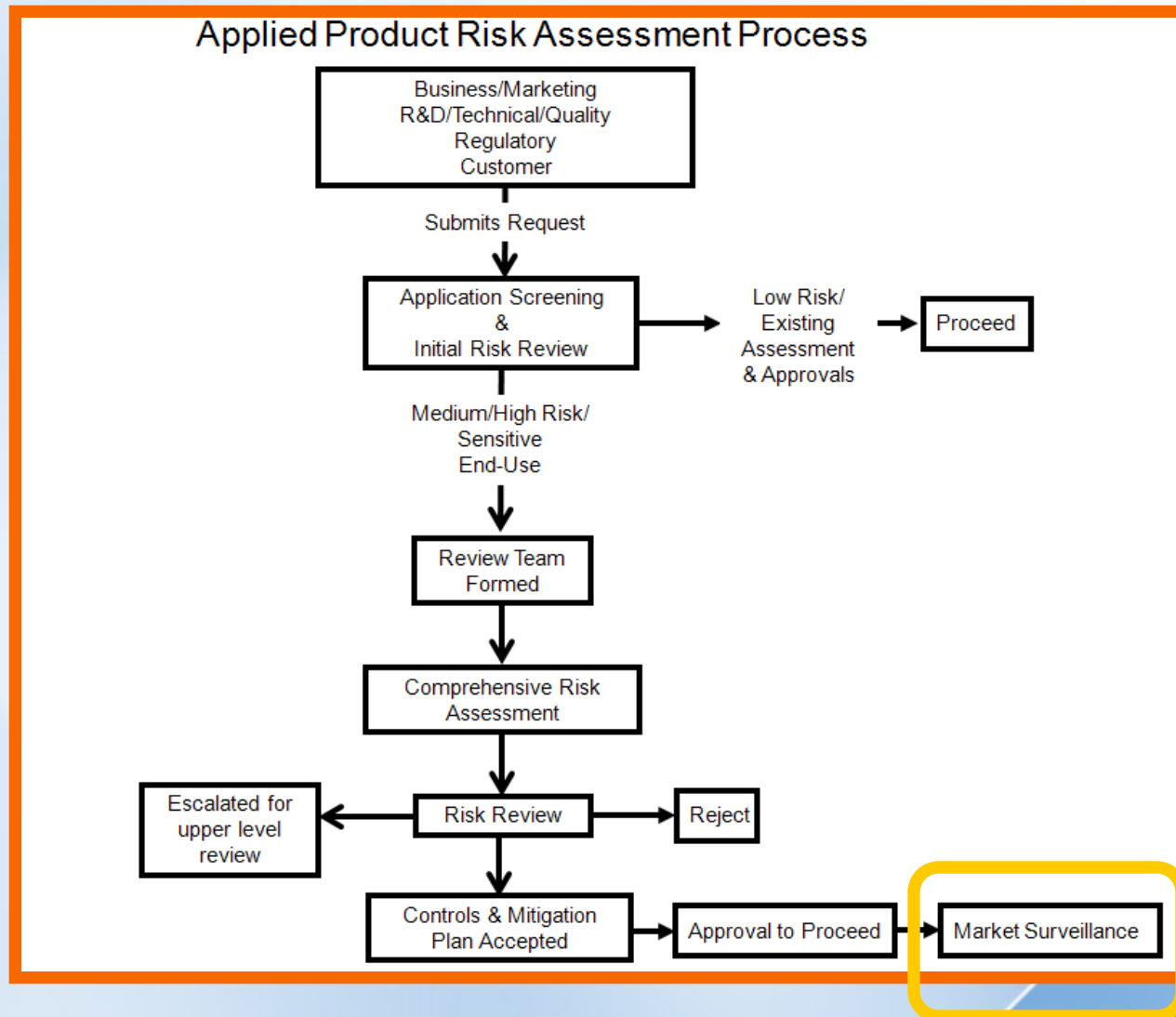
Mitigation Plan



### Requirements involving:

- ▶ Product Stewardship
- ▶ Legal
- ▶ Regulatory
- ▶ Quality
- ▶ Manufacturing
- ▶ Contractual Agreements

# ► Post Market Surveillance



# ▶ Post Market Surveillance

- ▶ Customer interaction with our:
  - Sales
  - Marketing
  - Customer Service
- ▶ Adverse events
- ▶ Complaints
- ▶ Legal claims
- ▶ Audits

## ▶ Summary

- ▶ Governing guiding principle & strategy
- ▶ Internal business tool
- ▶ Review of new products, significant changes, new end-uses
- ▶ Manage risk
- ▶ Mitigation plan and controls
- ▶ Market introduction review
- ▶ Expert review

# ▶ Acknowledgements

- ▶ Dr. E. Karl Enters- Global Product Stewardship Manager
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- ▶ Ashley Duffie- Associate General Counsel