



# Using CMMI to Improve Performance in Medical Device Software Engineering

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# Developing Medical Devices

- Innovations in Life Science
- Very Fulfilling Work
- Medical Devices are Regulated
- Market Approval Required
- Standards Certification Gates Commerce



# Regulations & Standards

- 21 CFR Part 820
- EU MDD
- ISO 13485
- ISO 14971
- IEC 62304
- & More



# Focus is Public Safety

- SOP's Required
- Heavy Planning Expected
- Adherence to Plans Expected
- Documents & Records Depict a Body of Evidence for Safety

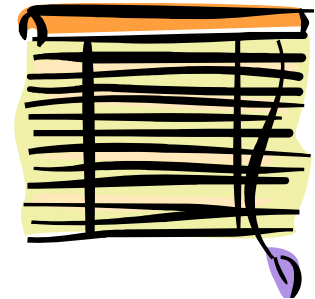


# Organizational Performance NOT Required

- Organizational Efficiency and Effectiveness  
Often Secondary Importance, or Omitted Completely
- Performance to Cost and Schedule Often  
Secondary Importance, or Omitted Completely
- Yet Performance is Critical due to Market Window

# Observation

Medical Device R&D Organizations are heavily focused on Satisfying Regulations and often lose focus on the Performance of Project Management and Engineering Processes



# What is CMMI?

- Capability Maturity Model Integrated
- World Class General Reference Model for Process Improvement in Product Development
- Process Requirements for Project Management, Engineering, Support, and Process Management

# CMMI

- Significant Focus on Process Institutionalization and Performance
- Improvement in Stages, Based on Philosophies of Deming and Crosby
- Successfully Applied Across Domains, Predominately in Software Engineering
- ROI in the range of 4 to 1

# Mapping CMMI to Medical Device Standards

- White Paper Provides a Comprehensive Summary
- Table 1: CMMI to IEC 62304 & ISO 13485
- Table 2: IEC 62304 to CMMI
- This Presentation Highlights Observations from the Mapping

# CMMI and Medical Device Stds Similarities

- Process Requirements
- Requirements Management
- Change Control
- Quality Assurance
- Risk Management
- Verification & Validation

# CMMI and Medical Device Stds Similarities

- Training
- Written Procedures
- Objective Evidence
- ISO 13485 Addresses Some of the Process Management Requirements

# Observations Project Management

## 1. Project Planning

- No estimation in IEC 62304
- No Planning for Budget & Schedule, Needed Training, or Stakeholder Involvement
- Reviewing Plans with Stakeholders, Resolving Resource Levels, nor Obtaining Commitment

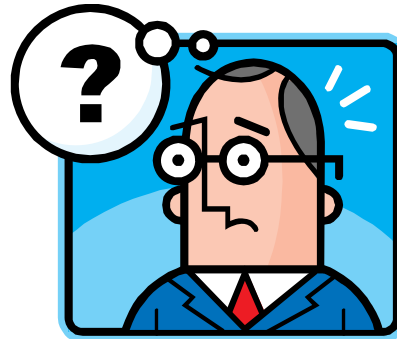
# Observations Project Management

## 2. Project Monitoring and Control

- No PMC in IEC 62304
- 3485 Systematic Reviews, but no focus on Commitments, Planning Parameters, Project Risks
- No Resolving Project Issues (SG2)

# Observations Project Management

Can Poor Project Management Discipline Lead  
to Unsafe Products?



# Observations

## Project Management

### 3. Supplier Agreement Management

- No SAM in IEC 62304
- ISO 13485 Light Mention of Selection of Suppliers and Evaluation of Purchased Product

# Observations Project Management

## 4. Integrated Project Management

- IEC 62304 has Planning for Standards, Methods, and Tools
- ISO 13485 More Focused on Product than Project
- ISO 13485 Falls Short - Tailoring, Integrated Planning, Re-use, and Collaboration with ALL Stakeholders Stressed in CMMI
- No IPPD (Integrated Product and Process Development) in ISO 13485 or IEC 62304

# Observations Project Management

## 5. Risk Management

- IEC 62304 Does Not Address “Project” Risk Management
- ISO 13485 Addresses Risk Management of Nonconformance, Weak in Project Risk Management

# Observations Project Management

## 6. Quantitative Project Management

- Section 7.1.a, ISO 13485 “Determine Quality Objectives and Requirements for the Product”
- CMMI Requires the Use of Organizational Process Performance Practices to Set and Manage Quantitative Project Objectives

# Observations Engineering

## 1. Requirements Management

IEC 62304 does not Specifically Address the Identification of Inconsistencies Between Requirements and Project Work (CMMI SP 1.5)

# Observations Engineering

## 2. Requirements Development

- Customer requirements in scope for ISO 13485
- Product and Product Component Requirements in scope for IEC 62304
- Missing
  - Establish Operational Concepts
  - Establish a Definition of Required Functionality
  - Achieve Balance
  - Validate

# Observations Engineering

## 3. Design

Good Alignment in IEC 62304, But Missing:

- Develop and Select Alternative Technical Solutions
- Establishment of a Technical Data Package
- Perform Make/Buy/Reuse Analysis
- Develop Product Support Documentation

# Observations Engineering

## 4. Product Integration

Good Alignment in IEC 62304, But Missing:

- Planning for Integration.

*It is Very Important to Identify  
Integration Sequence, Environment,  
and Success Criteria Early*

# Observations Engineering

## 5. Verification

- IEC 62304 Does Not Dictate Verification Methods
- CMMI Requires Peer Reviews and the Analysis of Peer Review Data

# Observations Engineering

## 6. Validation

- IEC 62304 Does Not Cover Validation
- ISO 13485 - No Evaluation of Validation Results - Critical Activity



*Potentially an Accidental  
Omission in the ISO Standard*

# Observations Support

## 1. Quality Assurance

- Good Alignment
- One Weakness in IEC 62304 and ISO 13485 is the Lack of Emphasis on the Establishment of Records

# Observations Support

## 2. Measurement and Analysis

- No MA in IEC 62304
- ISO 13485 does not Provide the Guidance Necessary to Implement and Maintain an Effective Measurement Process

# Observations Support

## 3. Configuration Management

- Good alignment of IEC 62304 but Lacks Configuration Audits
- ISO 13485 not as Strong in CM

*A hint that software requires more CM discipline*

# Observations Support

## 4. Decision Analysis

- IEC 62304 and ISO 13485 do not Provide any Guidance for Decision Analysis

*Do We Make Important Decisions in Engineering Medical Devices?*

- Employing a Formal Decision Analysis Process can have a Significant Positive Impact on Costs, Schedule, and Quality (including safety)

# Observations Support

## 5. Causal Analysis and Resolution

- No CAR in IEC 62304
- ISO 13485 Requires the Statistical Analysis of Data to Determine Potential Causes of Nonconformities

*Without the Support of OPP (Organizational Process Performance), QPM (Quantitative Project Management), and OID (Organizational Innovation and Deployment), the Effectiveness of this Analysis is Questionable*

# Observations Process Management

- No Process Management in IEC 62304
- It is Left to the QMS

# Observations Process Management

## 1. Determine Process Needs

- ISO 13485 Requires the Identification of Needed Processes
- ISO 13485 Requires Audits, but not Appraisal of the Organization's Processes
- ISO 13485 - No Selection and Prioritization Necessary to Achieve Progress

# Observations Process Management

## 2. Process Action Planning

- ISO 13485 Light Mention of Requirements for Process Sequence, Criteria, and Methods
- Does not Emphasize Strategic Planning – *“Begin with the End in Mind”* - SWOT Analysis
- Does not Address the Need for Planning Process Improvements

# Observations Process Management

## 3. Process Deployment

- ISO 13485 does not Address Deployment of Processes
- Deployment of New and Modified Processes must be Meticulously Managed

# Observations Process Management

## 4. Process Assets

- Concept of Process Assets Missing in ISO 13485

Process Assets are Artifacts that Relate to Describing, Implementing, and Improving Processes .....  
..... like Policies, Defined Processes, Checklists,  
Lessons-Learned Documents, Templates, Standards,  
Procedures, Plans, and Training Materials

# Observations Process Management

## 5. Standard Processes with Tailoring Methods and Criteria

- Weak Mention in ISO 13485 section 7.1.b  
*"Establish Processes, Documents, and Provide Resources Specific to the Product"*

Tailoring Guidelines allow the Organization to Maintain Standard Processes and Fit them to Meet Objectives, Constraints and Environment of Projects

# Observations Process Management

## 6. Measurement Repository

- Concept is not addressed in ISO 13485
- Measurement Mentioned, But Does Not Address Structure - Organization - Archival - Readily Available over Time

# Observations Process Management

## 7. Training

- ISO 13485 Requires Delivery, Records Management, and Assessment of Training Effectiveness
- Does not Specifically Address Training Infrastructure (Capability) and Division of Responsibility for Training

# Observations Process Management

## 8. IPPD (Integrated Product and Process Development)

- A Hint of IPPD in ISO 13485 Section 7.3.1.c.  
“manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility”
- IPPD is an Addition in CMMI Enabling Timely Collaboration of Relevant Stakeholders

# Observations Process Management

## 9. Process Performance

- Light Mention in ISO 13485 Sections 5.1.c and 5.4.1 to Ensure that Quality Objectives are Established
- CMMI OPP (Organizational Process Performance) - Use of Historical Data in Measurement Repository to Build Performance Baselines and Models
- CMMI OID (Organizational Innovation and Deployment) - Enables the Selection and Deployment of Improvements to Enhance an Organization's Ability to Meet its Quality and Process Performance

# Observations Generic Practices

- GG2 Generic Practices 2.1 – 2.10

Found Mainly in ISO 13485 and Not In IEC 62304

- GG3 – GG5 Not Addressed

# Observations Generic Practices

Most Important Difference:

**CMMI Generic Practices Apply  
to ALL Processes**

# Reverse Mapping – Table 2

- Reverse Mapping Shows How Well CMMI Covers the Requirements of IEC 62304
- Specific Requirements not Addressed can Fit Very Well within the Process Framework

# Experience Reports

- Trialstat Corporation – Case Study in CMMI Book (Guidelines for Process Integration and Product Improvement, Second Edition)
- Little Else is Known
- Competitive Secret?

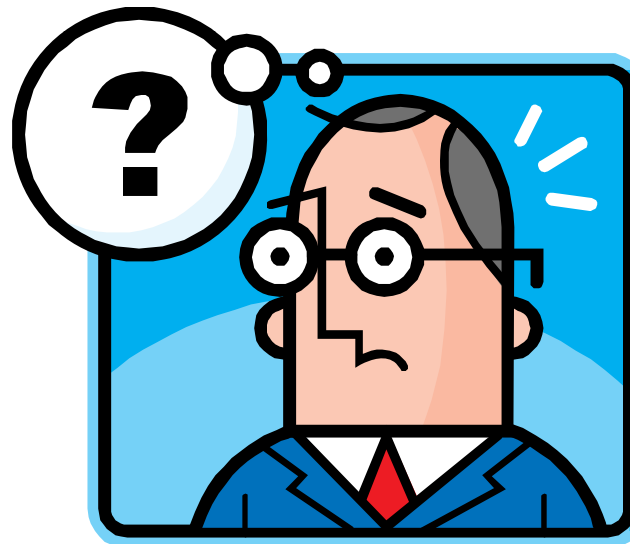
# Summary

- The Nature of the CMMI Requirements is Performance – Organizational Effectiveness and Efficiency
- Aligning with CMMI Presents a ***Humongous*** Opportunity for Medical Device R&D Teams

# Summary

- The Added Value is in Process Areas that Reduce Risk for the Organization and Projects, and the Generic Goals & Practices
- CMMI Provides the Framework to Support Medical Device Engineering Processes

# Questions?



# Materials

Slides and the White Paper at:

[www.davidwalkerspcs.com/downloads](http://www.davidwalkerspcs.com/downloads)

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