Introduction

The Capability Maturity Model Integration® (CMMI®) has been successfully applied for process improvement in various product development environments for almost 10 years, with its predecessor, the Software Capability Maturity Model (CMM-SW) used successfully in the 1990's. The Software Engineering Institute has provided reports on the successful use of the CMMI in aerospace, defense, government, financial, and insurance industry sectors. Little is known of adoption in medical device engineering.

This paper summarizes the comparison performed between the CMMI and the regulations and standards that drive software intensive medical device product development. The primary perspective is for medical device software engineering, where the most significant opportunity lies. This paper shows what is missed when medical device engineering teams chase ISO 13485 and IEC 62304 compliance without using CMMI to effectively manage processes.

The CMMI to IEC 62304 Mapping is provided at the end of this paper.

Definitions

First, a few definitions to set the context:

CMMI: Capability Maturity Model Integration
CMMI is a general reference model for process improvement in product development consisting of project management, engineering, support, and process management process requirements. Although applied across domains, the CMMI has most successfully been applied in software engineering.

IEC: International Electrotechnical Committee
IEC is a worldwide organization for standardization comprising national electrotechnical committees. IEC 62304 was prepared by a Joint Working Group of:

- Subcommittee (SC) 62A Common aspects of electrical equipment used in medical practice
- IEC Technical Committee (TC) 62, Electrical equipment in medical practice,
- ISO Technical Committee (TC) 210, Quality management and corresponding general aspects for medical devices
- Table C.5 was prepared by ISO/IEC JTC 1/SC 7, Software and system engineering.

IEC 62304: Medical Device Software - Software Life Cycle Processes
IEC 62304 defines the life cycle requirements for medical device software. The set of processes, activities and tasks establish a common framework for medical device software life cycle processes. Since it clarifies expectations for medical device software, this global consensus standard has become widely adopted since it's publication in 2006. It has been approved by the US FDA as a reference standard and will be required for CE Mark in the European Union by April 2010.

ISO: International Standards Organization
ISO is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this standard.

ISO 13485 Medical devices - Quality Management Systems - Requirements for Regulatory Purposes
Specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

ISO 14971 Medical devices – Application of Risk Management to Medical Devices
Specifies a process to identify hazards associated with medical devices, estimate and evaluate the associated risks, control these risks, and monitor the effectiveness of the controls.

Approach

The approach taken to perform the mapping was to align the CMMI practices with requirements of IEC 62304, then, fill in with the requirements of ISO 13485 where possible. The mapping from ISO 13485 to CMMI is not provided since that could be indirectly accomplished from the existing ISO 9001 "Quality management systems – Requirements" to CMMI mapping and the comparison to ISO 9001 provided within ISO 13485. The FDA 21 CFR Part 820, Quality System Regulation, is not mapped since ISO 13485 covers most of the relevant sections and compliance to ISO 13485 is assumed. The mapping therefore is relevant to global medical device companies.

Observations from the Mapping

This section highlights the important similarities and differences between the CMMI, IEC 62304 and ISO 13485.

Project Management

PjM 1. Estimation

No estimation in IEC 62304.

PjM 2. Project Planning

No planning for budget, schedule, needed training, or stakeholder involvement in IEC 62304 or ISO 13485. There is no focus on reviewing plans with stakeholders, resolving resource levels, nor obtaining commitment before kick-off.

PjM 3. Project Monitoring and Control

No PMC in IEC 62304. 3485 incorporates systematic reviews of design and development, but no focus on commitments, planning parameters, identified project risks, etc. No resolving project issues (SG2).

PjM 4. Supplier Agreement Management

No SAM in IEC 62304. ISO 13485 lightly mentions selection of suppliers and evaluation of purchased product.

PjM 5. Integrated Project Management

The only alignment for IEC 62304 is in planning for standards, methods, and tools. ISO 13485 does require identification of processes specific to the product (not project), quality system improvement, and communication with customers, but falls well short of the tailoring, integrated planning, re-use, and collaboration with ALL stakeholders. Clearly, ISO 13485 is more focused on product than the projects that maintain products. The third goal in CMMI Integrated Project Management has requirements supporting IPPD (Integrated Product and Process Development) is not manifested in ISO 13485 or IEC 62304.

PjM 6. Risk Management

IEC 62304 does not address “project” risk management. ISO 13485 addresses risk management of nonconformance, but is weak in support of fundamental project risk management. Risk management in medical device engineering is all about product safety and NOT about risks to schedule, commitments, budget, and overall project objectives.

It is very important to note that the CMMI Risk Management process area addresses “project” risks and not safety risks. A good discussion on this topic occurred on the Yahoo CMMI Process Improvement Discussion Group (http://tech.groups.yahoo.com/group/cmmi_process_improvement/) early in 2009. The CMMI, including model and appraisal methods, does not require the application of the Risk Management process area to safety. The CMMI is clearly focused on project risk management. Notwithstanding, proper use of the model (for process improvement as a primary objective) would suggest that an organization engineering regulated medical devices would apply the practices of the Risk Management process area to safety, and a few lead appraisers would require it.

Although IEC 62304 does align very well with the CMMI Risk Management practices with respect to safety, there are a few omissions that are left up to the requirements of ISO 14971 Medical Devices – Application of Risk Management to Medical Devices.

PjM 7. Quantitative Project Management

In section 7.1.a, ISO 13485 provides the requirement to “Determine quality objectives and requirements for the product”. This is the only mention of setting and managing objectives and again addresses only product and not project.

CMMI elaborates significantly here by requiring the use of Quantitative Project Management practices to set and manage quantitative project objectives based on an understanding of process performance achieved through the Organizational Process Performance practices.

Engineering

ENG 1. Requirements Management

Good alignment in ISO 13485, but IEC 62304 is missing SP 1.5 where inconsistencies between project work and requirements are identified. This is a common problem and can happen when requirements are changing or project management process is not effective.

ENG 2. Requirements Development

Customer requirements are addressed in ISO 13485, product and product component requirements are addressed in IEC 62304. Although IEC 62304 is strong in requirements analysis, a few important omissions in IEC 62304 are:

i. Establish operational concepts

ii. Establish a definition of required functionality

iii. Achieve balance

iv. Validate. Again, IEC 62304 does not address validation.

ENG 3. Software Design

IEC 62304 is well aligned with CMMI in requirements for architecture, detailed designs, and interface designs. The following very important performance related requirements are missing:

i. Develop and select alternative technical solutions

ii. Establishment of a technical data package

iii. Perform make/buy/reuse analysis

iv. Develop product support documentation

The CMMI contains requirements for a formal decision analysis process that could help medical device designers to gather facts and data, analyze alternatives, make decisions, and record this decision data. Too often, engineers are quick to select a technical solution without weighing other alternatives. Without performing the make/buy/reuse analysis, the opportunity is lost to save money, shorten schedule, and reduce cycle time.

Medical device standards are not specific about certain types of engineering specifications that are necessary to support products. In the Technical Solution process area, the technical data package and product support documentation are described. Producing the necessary documentation is essential in efficiently maintain products and meeting customer expectations.

ENG 4. Product Integration

IEC 62304 is strong here. One weakness is the lack of planning for integration. It is very important to identify the integration sequence, environment, and success criteria early.

ENG 5. Verification

The word “verify” is used frequently in IEC 62304. The standard leaves it up to the manufacturer how to verify. The CMMI specifically calls out peer reviews and requires them. Naturally, a manufacturer would comply with IEC 62304 by selecting to perform peer reviews on certain work products. One very important performance related omission in IEC 62304 is the analysis of peer review data. The intent of this practice in the CMMI SP2.3 is to specifically look at the effort, pace, number of bugs found, etc, and make improvements based on what this data says.

ENG 6. Validation

IEC 62304 section 1.2 says “This standard does not cover validation”. To some, this may hit like a train. But the FDA’s misuse of the term “validation” over the years has led to significant confusion. The GPSV (General Principles of Software Validation, 2002, FDA) is a good example of how the term “software validation” includes in scope planning, requirements definition, architecture, verification, testing, traceability, configuration management, and many other aspects of good software engineering.

The CMMI’s definition of validation: “Confirmation that the product, as provided (or as it will be provided), will fulfill its intended use”. This is similar to IEEE and Wikipedia. Validation is evaluating a product or work product against intended uses in the intended environment.

Although ISO 13485 does mention the requirement to perform validation, it does not mention the evaluation of validation results, a critical activity and potentially an accidental omission in the standard.

It’s important to note that in section 5.1.3.b of IEC 62304, the software development plan must include procedures for coordinating the software development and the design and development validation.

Support

SUP 1. Quality Assurance

Good alignment of IEC 62304. One weakness is the lack of focus on establishing QA records as in CMMI PPQA SP 2.2.

SUP 2. Measurement and Analysis

No MA in IEC 62304. ISO 13485 is weak in measurement. It does not provide the guidance necessary to implement and maintain an effective measurement process.

SUP 3. Configuration Management

There is impressive alignment of IEC 62304 with CMMI. One minor weakness is the lack of configuration audits as in CMMI CM SP 3.2. Note that ISO 13485 is not as strong in CM……. a hint that software requires more CM discipline.

SUP 4. Decision Analysis

IEC 62304 and ISO 13485 do not provide any guidance for formal 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).

SUP 5. Causal Analysis and Resolution

Although scattered somewhat, ISO 13485 contains impressive alignment with CMMI Causal Analysis and Resolution in requiring the statistical analysis of data to determine potential causes of nonconformities. Without the support of the OPP (Organizational Process Performance), QPM (Quantitative Project Management), and OID (Organizational Innovation and Deployment), the effectiveness of this analysis is questionable.

Process Management

There are no process management requirements in IEC 62304. It is left to the quality management system, ie ISO 13485, which does contain a few of the Organizational Process Focus, Organizational Process Definition, and Organizational Training process requirements.

PcM 1. Determine Process Needs

ISO 13485 does require the identification of needed processes but does not address appraisal of the organization's processes and the selection and prioritization necessary to achieve progress.

PcM 2. Process Action Planning

ISO 13485 has a few requirements for process sequence, criteria, and methods, but does not address the need for planning process improvements.

PcM 3. Process Deployment

ISO 13485 does not discuss deployment of processes and is missing the concept of "process assets".

PcM 4. Process Assets

This concept is missing in ISO 13485. The CMMI separates standard processes from process assets. 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.

PcM 5. Standard Processes with Tailoring Methods and Criteria

There is a hint of tailoring in ISO 13485 section 7.1.b, but in general, this standard does not provide guidance on defining the organizations set of standard processes, sub-processes, and tailoring guidelines. The tailoring guidelines adapt the standard process to meet objectives, constraints, and environment of the project.

PcM 6. Measurement Repository

This concept is not addressed in ISO 13485. Measurement is addressed, but the structure, organization, and archival of measurements to keep them readily available over time is not defined. In CMMI, the measurement repository is a critical resource providing a stable and reliable source of information to drive fact based decisions. It is the measurement repository that gathers the data necessary to move to higher process maturity levels (4 and 5).

PcM 7. Training

ISO 13485 does address the delivery, records management, and assessment of the training effectiveness, but does not specifically address training infrastructure (capability) and division of responsibilities for training.

PcM 8. IPPD

It is pleasing to see that ISO 13485 does have a CMMI IPPD (Integrated Product and Process Development, *an optional set of CMMI practices enabling timely collaboration of relevant stakeholders*) requirement to determine responsibilities and authorities for design and development and manage the interfaces between different groups in section 7.3.1.c.

PcM 9. Process Performance

ISO 13485 contains some light requirements in sections 5.1.c and 5.4.1 to ensure that quality objectives are established, but comes no where close to the rigor of the CMMI Organizational Process Performance process area that requires the use of historical data in the measurement repository to build performance baselines and models to help the organization be more predictable and successful in meeting quality and performance objectives.

Also not addressed in medical device standards is the CMMI Organizational Innovation and Deployment process area which enables the selection and deployment of improvements that can enhance an organization's ability to meet its quality and process performance objectives based on a quantitative understanding of the organization's current quality and process performance.

Generic Practices

The CMMI Generic Practices are vital to institutionalizing the processes. At maturity level two, there are 10 generic practices that set requirements for institutionalizing a managed process. These 10 generic practices apply to all process areas in institutionalizing the managed process (maturity level 2).

Note that IEC 62304 contains very little alignment with these generic practices. Unless specified, below, there are no requirements in IEC 62304 for these CMMI elements.

GP 2.1. Policy

ISO 13485 is well aligned.

GP 2.2. Plan The Process

Both IEC 62304 and ISO 13485 contain planning for only a few of the processes, but do not cover others as explicitly required in CMMI.

GP 2.3. Provide Resources

ISO 13485 requires resources necessary to support the operation and monitoring of the processes. This is intended to apply in general to the quality system.

GP 2.4. Assign Responsibility

ISO 13485 requires the determination of responsibilities in general.

GP 2.5. Train The People

The section on training in ISO 13485 is weak. Although is does address identification of training needs, training, and records, it does not address the importance of establishing a training capability with supporting infrastructure as is emphasized in the CMMI.

GP 2.6. Manage Configurations

IEC 62304 contains requirements for configuration management, but its application of these requirements specifically to process areas is sparse. ISO 13485 contains requirements to maintain configurations but does not apply specifically to each process.

GP 2.7. Identify And Involve Relevant Stakeholders

ISO 13485 requires adequate representation in reviews and ISO 14971 requires involvement of relevant parties in the risk management process, but these standards do not require the identification and planning for involvement of all relevant stakeholders in other critical activities as identified in the CMMI.

GP 2.8. Monitor And Control The Process

ISO 13485 requires actions necessary monitor, measure, and analyze processes to achieve planned results and maintain the effectiveness of these processes. This requirement is well aligned with the CMMI but does not specifically require evidence for each process area.

GP 2.9. Objectively Evaluate Adherence

ISO 13485 requires internal audits to maintain the quality system compliance.

GP 2.10. Review Status With Higher Level Management

ISO 13485 section 5.5.2 nails this requirement pretty good. But, again, evidence is not required specifically for each process as in the CMMI.

GP 3.x – 5.x

The only alignment of ISO 13485 in CMMI Generic Goal 3 is in section 8.5.1 "Identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system" which aligns with GP 3.2 "Collect Improvement Information".

Medical device standards do not address any of the Generic Goals 4 and 5. ISO 13485 section 8.1 requires the use of statistical techniques as an applicable method for improving processes. This was not included in the mapping tables since it does not meet the intent of CMMI quantitative management and high maturity process management.

Reverse Mapping

Table 2 maps the IEC 62304 requirements to CMMI. Note that the CMMI performs well in providing a framework in which the various medical device software lifecycle requirements can fit. The mapping elements are mostly STRONG or MODERATE with CMMI lacking specific safety related requirements that have been derived over time though regulatory monitoring of software intensive medical devices.

Also note from Table 2 that IEC 62304 focuses on problem reports where the counterpart in CMMI is the change request (more general, but includes problem reports).

Conclusions

The CMMI-DEV significantly compliments medical device standards by focusing on process performance and closed loop improvement. There are placeholders for regulatory requirements such as design control and safety risk management.

Like ISO and other standards and industry guidance, the regulations do not provide adequate guidance on process institutionalization. CMMI emphases the importance of institutionalization through the application of the generic practices that must be accomplished for each process area. This observation alone suggests a profound opportunity for organizational process performance.

Regulations do not require project management practices. This is a massive gap in enabling performance, and potentially, a shortcoming in enabling safety management. It is when projects are not adequately managed that firefighting begins, overtime starts, burnout begins, shortcuts are taken, and safety mitigation falls apart. The CMMI requires project management discipline at the start with maturity level 2. CMMI project management practices become more standardized at maturity level 3, and more sophisticated at maturity level 4.

Regulations and standards do not require process focus, quantitative methods, or innovation and deployment. No guidance on the mechanics of improvement. ISO 13485 provides some essence of statistical measurement, but falls well short of the sophistication of the CMMI quantitative management and optimization process areas.

Although the CMMI Risk Management process area most often addresses project risk, it is well positioned to include safety risk management practices which follow very similar methodology.

Although alignment of the regulations with corporate operating procedures is assumed, project tailoring is not discussed in the regulations or standards. IEC 62304 introduces three safety classifications that vary the rigor of development practices. But the focus is on safety only, and falls well short of CMMI's Organizational Process Definition and Integrated Project Management.

The conclusion from this research is that medical device R&D organizations are a good fit with the CMMI model. The model provides a comprehensive framework on which medical device realization processes can thrive. The opportunity for performance improvement is profound. Medical device manufacturers are encouraged to see training in the CMMI-DEV and gain experience improving processes performance.

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Summary
Table 1 presents the mapping from CMMI-DEV to IEC 62304. In this table, since compliance to ISO 13485 is assumed for medical device manufacturers that market globally, mapping from CMMI to ISO 13485 is shown where the IEC 62304 is absent or weak.

Table 2 presents the mapping from IEC 62304 to CMMI-DEV. It is important to review both mappings to understand the scope, strengths, and weaknesses of both standards.

Alignment Strength

Primary Model: Model component listed on the left side of the table.
Secondary Model: Model component listed on the right side of the table.

STRONG: Secondary model fully satisfies the requirements of the primary model.
MODERATE: The secondary model minimally addresses the requirement of the primary model.
WEAK: Topic is minimally covered by the secondary model, but not required.

General Notes

- **CMMI has 356 practices at Maturity Level 3. IEC 62304 has 95 class C requirements, 89 class B requirements, and 43 class A requirements.**
- **Alignment is done for IEC 62304 Class C Requirements (or all requirements).**
- **IEC 62304 Table C.1 shows alignment of 13485 with IEC 62304, Table C.2 shows alignment of 14971 with 62304, and see section B.4.1 regarding the potential use of CMMI based quality system.**
- **IEC 62304 does NOT address validation. It is left to the system level and quality management system, ie ISO 13485.**
- **ISO 13485 mappings are marked in Green.**

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
	Level 2				
	Requirements Management				
SG 1	**Manage Requirements**				
SP 1.1	Obtain an Understanding of Requirements	5.2.3	Software requirements content	STRONG	
SP 1.2	Obtain Commitment to Requirements				
SP 1.3	Manage Requirements Changes	8.2.1	Approve CHANGE SPECIFICATIONS	STRONG	
SP 1.4	Maintain Bidirectional Traceability of Requirements	5.2.3	Include RISK CONTROL measures in software requirements	MODERATE	
		5.2.5	Update SYSTEM requirements	MODERATE	
		5.7.1	Establish tests for software requirements	MODERATE	
		7.3.3	Document TRACEABILITY	STRONG	But not bidirectional
SP 1.5	Identify Inconsistencies Between Project Work and Requirements				
	Project Planning				
SG1	**Establish Estimates**				
SP 1.1	Estimate the Scope of the Project				
SP 1.2	Establish Estimates of Work Product and Task Attributes				
SP 1.3	Define Project Lifecycle				
SP 1.4	Determine Estimates of Effort and Cost				

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
SG2	**Develop a Project Plan**				
SP 2.1	Establish the Budget and Schedule				
SP 2.2	Identify Project Risks				
SP 2.3	Plan for Data Management	5.1.8	Software configuration management planning	STRONG	
SP 2.4	Plan for Project Resources	5.1.4	Software development standards methods and tools planning	MODERATE	
SP 2.5	Plan for Needed Knowledge and Skills				
SP 2.6	Plan Stakeholder Involvement				
SP 2.7	Establish the Project Plan	5.1.1	Software development plan	MODERATE	
		6.1	Establish software maintenance plan	MODERATE	
SG 3	**Obtain Commitment to the Plan**				
SP 3.1	Review Plans That Affect the Project				
SP 3.2	Reconcile Work and Resource Levels	7.2.2.c	The organization has the ability to meet the defined requirements.	MODERATE	Ability to meet requirements. Does not imply the ability to reconcile.
SP 3.3	Obtain Plan Commitment				
	Project Monitoring & Control				
SG 1	**Monitor Project Against Plan**				
SP 1.1	Monitor Project Planning Parameters				
SP 1.2	Monitor Commitments				
SP 1.3	Monitor Project Risks				

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
SP 1.4	Monitor Data Management				
SP 1.5	Monitor Stakeholder Involvement				
SP 1.6	Conduct Progress Reviews	7.3.4	At suitable stages, systematic reviews of design and development shall be performed	MODERATE	Fits better in SP 1.7
SP 1.7	Conduct Milestone Reviews	5.8.6	Ensure activities and tasks are complete	WEAK	Weak. Only at release.
		7.3.4	At suitable stages, systematic reviews of design and development shall be performed	STRONG	
SG 2	**Manage Corrective Action to Closure**				No Project CA, only product.
SP 2.1	Analyze Issues				
SP 2.2	Take Corrective Action				
SP 2.3	Manage Corrective Action				
	Supplier Agreement Management				
SG 1	**Establish Supplier Agreements**				No SAM
SP 1.1	Determine Acquisition Type				
SP 1.2	Select Suppliers	7.4.1	Purchasing Process	MODERATE	
SP 1.3	Establish Supplier Agreements				
SG 2	**Satisfy Supplier Agreements**				
SP 2.1	Execute the Supplier Agreement				

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
SP 2.2	Monitor Selected Supplier Processes				
SP 2.3	Evaluate Selected Supplier Work Products	7.4.3	Verification of Purchased Product		
SP 2.4	Accept the Acquired Product				
SP 2.5	Transition Products				
	Process & Product Quality Assurance				
SG 1	**Objectively Evaluate Processes and Work Products**				
SP 1.1	Objectively Evaluate Processes	8.2.2	The organization shall conduct internal audits at planned intervals	STRONG	Only addresses processes
SP 1.2	Objectively Evaluate Work Products and Services				
SG 2	**Provide Objective Insight**				
SP 2.1	Communicate and Ensure Resolution of Noncompliance Issues	8.2.2.b	The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes	MODERATE	Missing “Communicate”.
SP 2.2	Establish Records				
	Measurement & Analysis				
SG 1	**Align Measurement and Analysis Activities**	8.4	**Analysis of data**	WEAK	CMMI provides much more guidance and scope.

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
SP 1.1	Establish Measurement Objectives				
SP 1.2	Specify Measures				
SP 1.3	Specify Data Collection and Storage Procedures				
SP 1.4	Specify Analysis Procedures				
SG 2	**Provide Measurement Results**	8.2.3	**Monitoring and measurement of processes**	MODERATE	Does not provide the guidance and scope that CMMI does.
		8.2.4.1	The organization shall monitor and measure the characteristics of the product		
SP 2.1	Collect Measurement Data				
SP 2.2	Analyze Measurement Data	9.6	Analyze problems for trends	WEAK	There may not be any data, just the reports.
SP 2.3	Store Data and Results				
SP 2.4	Communicate Results				
	Configuration Management				
SG 1	**Establish Baselines**				
SP 1.1	Identify Configuration Items	8.1.1	Establish means to identify CONFIGURATION ITEMS	STRONG	
		8.1.2	Identify SOUP		
		9.8	Test documentation contents		
SP 1.2	Establish a Configuration Management System	8.2.4	Provide means for TRACEABILITY of change	STRONG	

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
SP 1.3	Create or Release Baselines	5.1.11	Software CONFIGURATION ITEM control before VERIFICATION		
		5.8.4	Document released VERSIONS		
		5.8.5	Document how released software was created		
		5.8.7	Archive software		
		6.3.2	Re-release modified SOFTWARE SYSTEM		
		8.1.3	Identify SYSTEM configuration documentation		
		4.2.3.c	Ensure that changes and the current revision status of documents are identified	MODERATE	
SG 2	**Track and Control Changes**	7.3.7	**Control of design and development changes**	MODERATE	
SP 2.1	Track Change Requests	5.6.8	Use software problem resolution PROCESS		
		5.7.2	Use software problem resolution PROCESS	STRONG	
		5.8.2	Document known residual ANOMALIES		

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
		6.2.1.1	Monitor feedback		
		6.2.2	Use software problem resolution PROCESS		
		8.2.2	Implement changes		
		8.2.3	Verify changes		
		8.2.4	Provide means for TRACEABILITY of change		
		4.2.3.a	Review and approve documents for adequacy prior to issue	MODERATE	
SP 2.2	Control Configuration Items	6.2.3	Analyze CHANGE REQUESTS		
		6.2.4	CHANGE REQUEST approval		
		7.4.1	Analyze changes to MEDICAL DEVICE SOFTWARE with respect to SAFETY	STRONG	
		7.4.2	Analyze impact of software changes on existing RISK CONTROL measures		
		7.4.3	Perform RISK MANAGEMENT ACTIVITIES based on analyses		

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
		8.2.1	Approve CHANGE REQUESTS		
		9.4	Use change control process		
SG 3	**Establish Integrity**				
SP 3.1	Establish Configuration Management Records	5.8.4	Document released VERSIONS	STRONG	
		5.8.5	Document how released software was created		
		5.8.7	Archive software		
		8.3	Configuration status accounting		
		9.5	Maintain records		
		4.2.3.e	Ensure that documents remain legible and readily identifiable	MODERATE	
SP 3.2	Perform Configuration Audits	5.8.8	Assure repeatability of software release	Moderate	Only part of configuration audit
	Level 3				
	Requirements Development				
SG 1	**Develop Customer Requirements**				
SP 1.1	Elicit Needs				

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
SP 1.2	Develop the Customer Requirements	7.2.1.a	Determine requirements specified by the customer, including the requirements for delivery and post-delivery activities	STRONG	
		7.2.1.c	Determine statutory and regulatory requirements related to the product		
		7.2.1.d	Determine any additional requirements determined by the organization		
SG 2	**Develop Product Requirements**				
SP 2.1	Establish Product and Product Component Requirements	5.3.4	Specify SYSTEM hardware and software required by SOUP item	WEAK	CMMI clarifies the decomposition of customer requirements, product requirements, and product component requirements.
		5.2.1	Define and document software requirements from SYSTEM requirements	STRONG	
		7.2.1.b	Determine requirements not stated by the customer but necessary for specified or intended use, where known	MODERATE	Does not imply layered requirements, an important strength of CMMI.
		7.2.2.a	Ensure that product requirements are defined and documented		
		7.3.2	**Design and development inputs**		
SP 2.2	Allocate Product Component Requirements	5.3.3	Specify functional and performance requirements of SOUP item	STRONG	

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
		5.2.1 .	Define and document software requirements from SYSTEM requirements		
		5.4.1	Refine SOFTWARE ARCHITECTURE into SOFTWARE UNITS		
SP 2.3	Identify Interface Requirements	5.3.2	Develop an ARCHITECTURE for the interfaces of SOFTWARE ITEMS	STRONG	
		5.3.5	Identify segregation necessary for RISK CONTROL	MODERATE	Addresses only the safety aspect of the intent of this practice
SG 3	**Analyze and Validate Requirements**				
SP 3.1	Establish Operational Concepts and Scenarios				
SP 3.2	Establish a Definition of Required Functionality				
SP 3.3	Analyze Requirements	5.2.6	Verify software requirements	STRONG	Good criteria included
SP 3.4	Analyze Requirements to Achieve Balance				
SP 3.5	Validate Requirements				
	Technical Solution				
SG 1	**Select Product Component Solutions**				
SP 1.1	Develop Alternative Solutions and Selection Criteria				
SP 1.2	Select Product Component Solutions				

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
SG 2	**Develop the Design**	7.3.3	**Design and development outputs**	MODERATE	CMMI provides much more guidance.
SP 2.1	Design the Product or Product Component	5.4.2	Develop detailed design for each SOFTWARE UNIT	STRONG	
		5.3.1	Transform software requirements into an ARCHITECTURE		
SP 2.2	Establish a Technical Data Package				
SP 2.3	Design Interfaces Using Criteria	5.4.3	Develop detailed design for interfaces	MODERATE	Does not include criteria
		5.3.2	Develop an ARCHITECTURE for the interfaces of SOFTWARE ITEMS		
SP 2.4	Perform Make, Buy, or Reuse Analyses				
SG 3	**Implement the Product Design**				
SP 3.1	Implement the Design	5.5.1	Implement each SOFTWARE UNIT	STRONG	
SP 3.2	Develop Product Support Documentation	6.1	Establish software maintenance plan	WEAK	
	Product Integration				
SG 1	**Prepare for Product Integration**	5.1.5	Software integration and integration testing planning	WEAK	Weak, not specific.

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
SP 1.1	Determine Integration Sequence				
SP 1.2	Establish the Product Integration Environment				
SP 1.3	Establish Product Integration Procedures and Criteria				
SG 2	**Ensure Interface Compatibility**				
SP 2.1	Review Interface Descriptions for Completeness	5.3.6	Verify software ARCHITECTURE	STRONG	
SP 2.2	Manage Interfaces				
SG 3	**Assemble Product Components and Deliver the Product**				
SP 3.1	Confirm Readiness of Product Components for Integration	5.3.6	Verify software ARCHITECTURE	MODERATE	Readiness implies defined criteria
		5.4.4	Verify detailed design		
		5.5.3	SOFTWARE UNIT acceptance criteria		
SP 3.2	Assemble Product Components	5.6.1	Integrate SOFTWARE UNITS	STRONG	
SP 3.3	Evaluate Assembled Product Components	5.6.2 .	Verify software integration	STRONG	
		5.6.3	Test integrated software		

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
		5.6.6	Conduct regression tests		
		5.6.7	Integration test record contents		
		5.7.3	Retest after changes		
		5.7.5	SOFTWARE SYSTEM test record contents		
		7.1.d	Determine records needed to provide evidence that the realization processes and resulting product meet requirements	MODERATE	
SP 3.4	Package and Deliver the Product or Product Component	5.8.4	Document released VERSIONS	MODERATE	Does not address actual delivery
	Verification				
SG 1	**Prepare for Verification**				
SP 1.1	Select Work Products for Verification	5.2.6	Verify software requirements	STRONG	Although it does not address selection, the primary work products are listed.
		5.7.1	Establish tests for software requirements		
		5.3.6	Verify software ARCHITECTURE		
		5.4.4	Verify detailed design		
		5.5.5	SOFTWARE UNIT VERIFICATION		

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
		5.6.5	Verify integration test procedures		
		5.7.4	Verify SOFTWARE SYSTEM testing		
		7.3.1	Verify RISK CONTROL measures		
		8.2.3	Verify changes		
SP 1.2	Establish the Verification Environment	5.1.4	Software development standards	MODERATE	Close, but it lists specific things and seems to leave out test equipment and lab environment.
		5.6.7	Integration test record contents		
		5.7.5	SOFTWARE SYSTEM test record contents		
SP 1.3	Establish Verification Procedures and Criteria	5.1.6	Software VERIFICATION planning	STRONG	
		9.8	Test documentation contents		
		5.6.4	Integration testing content		
		5.5.2	Establish SOFTWARE UNIT VERIFICATION PROCESS		
		5.5.3	SOFTWARE UNIT acceptance criteria		
		5.5.4	Additional SOFTWARE UNIT acceptance criteria		
SG 2	**Perform Peer Reviews**	7.3.5	**Design and development verification**	WEAK	Very little guidance in 13485
SP 2.1	Prepare for Peer Reviews	5.1.6	Software VERIFICATION planning	MODERATE	Not specific to peer reviews

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
SP 2.2	Conduct Peer Reviews	5.2.6	Verify software requirements		
		5.3.6	Verify software ARCHITECTURE		
		5.4.4	Verify detailed design		
		5.5.5	SOFTWARE UNIT VERIFICATION		
		5.6.5	Verify integration test procedures		
		5.7.4	Verify SOFTWARE SYSTEM testing		
		7.3.1	Verify RISK CONTROL measures		
		8.2.3	Verify changes		
SP 2.3	Analyze Peer Review Data	5.8.1	Ensure software VERIFICATION is complete	MODERATE	The CMMI practice is addressing the data regarding performance of peer reviews.
		5.8.2	Document known residual ANOMALIES		
		5.8.3	EVALUATE known residual ANOMALIES		
SG 3	**Verify Selected Work Products**				
SP 3.1	Perform Verification	5.7.3	Retest after changes	STRONG	
		5.6.6	Conduct regression tests		
		5.3.6	Verify software ARCHITECTURE		

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
		5.4.4	Verify detailed design		
		5.5.5	SOFTWARE UNIT VERIFICATION		
		7.3.1	Verify RISK CONTROL measures		
		5.6.7	Integration test record contents		
		5.7.5	SOFTWARE SYSTEM test record contents		
		5.6.3	Test integrated software		
		9.7	Verify software problem resolution		
SP 3.2	Analyze Verification Results	5.8.1	Ensure software VERIFICATION is complete		
		5.8.2	Document known residual ANOMALIES	STRONG	
		5.8.3	EVALUATE known residual ANOMALIES		
		7.1.d	Determine records needed to provide evidence that the realization processes and resulting product meet requirements	MODERATE	Scope is more narrow.
	Validation				

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
SG 1	**Prepare for Validation**	5.1.3	Software development plan reference to SYSTEM design and development	WEAK	IEC 62304 does not address Validation, only requires a reference to validation performed at a system level, addressed at the ISO 13486 QMS Level.
SP 1.1	Select Products for Validation				
SP 1.2	Establish the Validation Environment				
SP 1.3	Establish Validation Procedures and Criteria				
SG 2	**Validate Product or Product Components**				
SP 2.1	Perform Validation	7.3.6	**Design and development validation**	STRONG	
SP 2.2	Analyze Validation Results				
	Organizational Process Focus				Not Addressed in 62304
SG 1	**Determine Process Improvement Opportunities**				
SP 1.1	Establish Organizational Process Needs	4.1.a	Identify the processes needed for the quality management system and their application throughout the organization	STRONG	
SP 1.2	Appraise the Organization's Processes				
SP 1.3	Identify the Organization's Process Improvements				
SG 2	**Plan and Implement Process Improvements**				
SP 2.1	Establish Process Action Plans				

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
SP 2.2	Implement Process Action Plans	4.1.b	Determine the sequence and interaction of these processes	MODERATE	Doesn't really address the planning and acting on the plan.
		4.1.c	Determine criteria and methods needed to ensure that both the operation and control of these processes are effective		
SG 3	**Deploy Organizational Process Assets and Incorporate Lessons Learned**				
SP 3.1	Deploy Organizational Process Assets				
SP 3.2	Deploy Standard Processes				
SP 3.3	Monitor Implementation	8.5.1	Ensure and maintain the continued suitability and effectiveness of the quality management	STRONG	
SP 3.4	Incorporate Process-Related Experiences into the Organizational Process Assets	8.5.1	Identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system	MODERATE	CMMI requires more than just process improvements. Lessons learned, examples of good and bad process artifacts, metrics, etc are expected to be collected.
	Organizational Process Definition				Not Addressed
SG 1	**Establish Organizational Process Assets**				
SP 1.1	Establish Standard Processes	4.2.1.c	Documented procedures required by this International Standard.	MODERATE	Standard processes can be outside of the 13485 scope.

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
SP 1.2	Establish Lifecycle Model Descriptions	4.2.1.d	Documents needed by the organization to ensure the effective planning, operation, and control of its processes.	MODERATE	
SP 1.3	Establish Tailoring Criteria and Guidelines	7.1.b	Determine the need to establish processes, documents, and provide resources specific to the product	MODERATE	Project, not product.
SP 1.4	Establish the Organization's Measurement Repository				
SP 1.5	Establish the Organization's Process Asset Library				
SP 1.6	Establish Work Environment Standards	6.4	**Work environment**	STRONG	
	IPPD Addition				
SG 2	**Enable IPPD Management**				
SP 2.1	Establish Empowerment Mechanisms				
SP 2.2	Establish Rules and Guidelines for Integrated Teams				
SP 2.3	Balance Team and Home Organization Responsibilities	7.3.1.c	Determine the responsibilities and authorities for design and development & "…manage the interfaces between different groups…"	STRONG	
	Organizational Training				Not Addressed in 62304
SG 1	**Establish an Organizational Training Capability**				

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
SP 1.1	Establish the Strategic Training Needs	6.2.2.a	Determine the necessary competence for personnel performing work affecting product quality	MODERATE	More than product quality, CMMI addresses also process capability
SP 1.2	Determine Which Training Needs Are the Responsibility of the Organization				
SP 1.3	Establish an Organizational Training Tactical Plan				
SP 1.4	Establish Training Capability				
SG 2	**Provide Necessary Training**				
SP 2.1	Deliver Training	6.2.2.b	Provide training or take other actions to satisfy these needs	STRONG	
SP 2.2	Establish Training Records	6.2.2.e	Maintain appropriate records of education, training, skills, and experience	STRONG	
SP 2.3	Assess Training Effectiveness	6.2.2.c	Evaluate the effectiveness of the actions taken	STRONG	
	Decision Analysis & Resolution				Not Addressed
SG 1	**Evaluate Alternatives**				
SP 1.1	Establish Guidelines for Decision Analysis				
SP 1.2	Establish Evaluation Criteria				
SP 1.3	Identify Alternative Solutions				
SP 1.4	Select Evaluation Methods				
SP 1.5	Evaluate Alternatives				

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
SP 1.6	Select Solutions				
	Integrated Project Management				Not Addressed
SG 1	**Use the Project's Defined Process**				
SP 1.1	Establish the Project's Defined Process	7.1.b	Determine the need to establish processes, documents, and provide resources specific to the product	MODERATE	Product, not project as in CMMI, and defined process provides more guidance.
SP 1.2	Use Organizational Process Assets for Planning Project Activities	5.1.4	Software development standards, methods and tools planning	WEAK	SP 1.2 is much more
		7.1.b	Determine the need to establish processes, documents, and provide resources specific to the product	MODERATE	Product, not project as in CMMI
SP 1.3	Establish the Project's Work Environment	6.4	Work environment	MODERATE	Product, not project as in CMMI
SP 1.4	Integrate Plans				
SP 1.5	Manage the Project Using the Integrated Plans				
SP 1.6	Contribute to the Organizational Process Assets	8.5.1	Identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system	MODERATE	It fits, but only part of the picture.
SG 2	**Coordinate and Collaborate with Relevant Stakeholders**	7.2.3	Determine and implement effective arrangements for communicating with customers	WEAK	Weak…. Doesn't include all stakeholders
SP 2.1	Manage Stakeholder Involvement				

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
SP 2.2	Manage Dependencies				
SP 2.3	Resolve Coordination Issues				
	IPPD Addition				
SG 3	**Apply IPPD Principles**				
SP 3.1	Establish the Project's Shared Vision				
SP 3.2	Establish the Integrated Team Structure				
SP 3.3	Allocate Requirements to Integrated Teams				
SP 3.4	Establish Integrated Teams				
SP 3.5	Ensure Collaboration among Interfacing Teams				
	Risk Management				
SG 1	**Prepare for Risk Management**	8.5.3	**Preventive action**	MODERATE	
SP 1.1	Determine Risk Sources and Categories	7.1.2 7.1.3 7.1.4	Identify potential causes of contribution to a hazardous situation EVALUATE published SOUP ANOMALY lists Document potential causes	STRONG	
SP 1.2	Define Risk Parameters				Left to 14971
SP 1.3	Establish a Risk Management Strategy				Left to 14971

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
SG 2	**Identify and Analyze Risks**	5.8.3 6.2.1.3 7.1.4 7.1.5 7.3.2 7.1.1	EVALUATE known residual ANOMALIES Evaluate PROBLEM REPORT'S affects on SAFETY Document potential causes Document sequences of events Document any new sequences of events Identify SOFTWARE ITEMS that could contribute to a hazardous situation	STRONG	See also ISO 14971.
SP 2.1	Identify Risks	7.2.2	RISK CONTROL measures implemented in software	STRONG	
SP 2.2	Evaluate, Categorize, and Prioritize Risks	8.5.3.b	Evaluating the need for action to prevent occurrence of nonconformities	WEAK	A very small piece of risk management.
SG 3	**Mitigate Risks**	5.2.3	Include RISK CONTROL measures in software requirements		
SP 3.1	Develop Risk Mitigation Plans	7.2.1	Define RISK CONTROL measures	STRONG	
SP 3.2	Implement Risk Mitigation Plans	5.2.4	Re-EVALUATE MEDICAL DEVICE RISK ANALYSIS	MODERATE	Implies follow up on mitigation plans.
		8.5.3.e	Reviewing preventive action taken and its effectiveness	MODERATE	
	Level 4				
	Quantitative Project Management				
SG 1	**Quantitatively Manage the Project**				

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
SP 1.1	Establish the Project's Objectives	7.1.a	Determine quality objectives and requirements for the product	WEAK	Product, but not project
SP 1.2	Compose the Defined Process				
SP 1.3	Select the Subprocesses that Will Be Statistically Managed				
SP 1.4	Manage Project Performance				
SG 2	**Statistically Manage Subprocess Performance**				
SP 2.1	Select Measures and Analytic Techniques				
SP 2.2	Apply Statistical Methods to Understand Variation				
SP 2.3	Monitor Performance of the Selected Subprocesses				
SP 2.4	Record Statistical Management Data				
	Organizational Process Performance				
SG 1	**Establish Performance Baselines and Models**				
SP 1.1	Select Processes				
SP 1.2	Establish Process-Performance Measures				
SP 1.3	Establish Quality and Process-Performance Objectives	5.1.c	Ensuring that quality objectives are established	MODERATE	Does not imply quantitative management.
		5.4.1	**Quality objectives**		
SP 1.4	Establish Process-Performance Baselines				

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
SP 1.5	Establish Process-Performance Models				
	Level 5				
	Organizational Innovation & Deployment				
SG 1	**Select Improvements**				
SP 1.1	Collect and Analyze Improvement Proposals				
SP 1.2	Identify and Analyze Innovations				
SP 1.3	Pilot Improvements				
SP 1.4	Select Improvements for Deployment				
SG 2	**Deploy Improvements**				
SP 2.1	Plan the Deployment				
SP 2.2	Manage the Deployment				
SP 2.3	Measure Improvement Effects				
	Causal Analysis & Resolution				
SG 1	**Determine Causes of Defects**				
SP 1.1	Select Defect Data for Analysis	8.4	Analysis of data	STRONG	
		8.1	This shall include determination of applicable methods, including statistical techniques, and the extent of their use	STRONG	

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
		8.5.2.a	Reviewing nonconformities	MODERATE	Does not imply quantitative management.
SP 1.2	Analyze Causes	8.4	Analysis of data	MODERATE	Does not imply quantitative management.
		8.1	This shall include determination of applicable methods, including statistical techniques, and the extent of their use	STRONG	
		8.5.2.b	Determining the causes of nonconformities	STRONG	
SG 2	**Address Causes of Defects**				
SP 2.1	Implement the Action Proposals	8.5.2.d	Determining and implementing action needed	MODERATE	Does not imply quantitative management.
SP 2.2	Evaluate the Effect of Changes	8.5.2.f	Reviewing corrective action taken and its effectiveness	MODERATE	Does not imply quantitative management.
SP 2.3	Record Data	8.5.2.e	Recording of the results of any investigation and of action taken	MODERATE	Does not imply quantitative management.
	Generic Goals				
GG 1	**Achieve Specific Goals**				
	GP 1.1 Perform Specific Practices				
GG 2	**Institutionalize a Managed Process**				
GP 2.1	Establish an Organizational Policy	4.2.1.a	Documented statements of a quality policy and quality objectives	STRONG	
		5.1.b	Establishing the quality policy		

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
		5.3	**Quality policy**		
GP 2.2	Plan the Process	5.1.5 5.1.6 5.1.7 5.1.9 6.3.1	Software integration and integration testing planning Software VERIFICATION planning Software RISK MANAGEMENT planning Software configuration management planning Use established PROCESS to implement modification	WEAK	Does not cover other process areas
		5.4.2	**Quality management system planning**	WEAK	VER, VAL, PMC, PPQA ENG process areas Does not cover other process areas
		7.1.c	Required verification, validation, monitoring, inspection, and test activities specific to the product and the criteria for product acceptance		
		7.3.1	**Design and development planning**		
GP 2.3	Provide Resources	4.1.d	ensure the availability of resources and information necessary to support the operation and monitoring of these processes	STRONG	
		5.1.e	Ensuring the availability of resources		

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
		6.1	**Provision of resources**		
GP 2.4	Assign Responsibility	5.5.1	**Responsibility and authority**	MODERATE	Not specific to each process area
		7.3.1.c	Determine the responsibilities and authorities for design and development		
GP 2.5	Train People	6.2.2	**Competence, awareness, and training**	WEAK	Not specific to each process area
GP 2.6	Manage Configurations	5.1.2 5.1.8 5.1.9 5.1.10 8.1	Keep software development plan updated Software configuration management planning Documentation planning Supporting items to be controlled Configuration Identification	MODERATE	62304 is much more narrow in scope here.
		5.4.2.b	Integrity of the quality management system is maintained when changes to the quality management system are planned and implemented	MODERATE	Not specific to each process area
GP 2.7	Identify and Involve Relevant Stakeholders	7.3.4	Design and development review	WEAK	Only addresses stakeholder involvement in reviews.
		9.3	Advise relevant parties	WEAK	Only notifies relevant stakeholders of safety issues.
GP 2.8	Monitor and Control the Process	5.1.2	Keep software development plan updated	MODERATE	Only PP, Not specific to each process area
		4.1.f	Implement actions necessary to achieve planned results and maintain the effectiveness of these processes	MODERATE	Not specific to each process area

Table 1 - Mapping CMMI to IEC 62304					
CMMI	**Description**	**62304**	**Description**	**Alignment Strength**	**Observations**
		4.1.e	Monitor, measure, and analyze these processes		
		8.2	Monitoring and measurement	MODERATE	Not specific to each process area
GP 2.9	Objectively Evaluate Adherence	8.2.2	**Internal audit**	WEAK	Not specific to each process area
GP 2.10	Review Status with Higher Level Management	5.1.d	Conducting management reviews	WEAK	Not specific to each process area
		5.5.2	**Management representative**	STRONG	
		5.6.2	**Review input**		
GG 3	**Institutionalize a Defined Process**				
GP 3.1	Establish a Defined Process				
GP 3.2	Collect Improvement Information	8.5.1	Identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system	STRONG	
GG 4	**Institutionalize a Quantitatively Managed Process**				
GP 4.1	Establish Quantitative Objectives for the Process				
GP 4.2	Stabilize Subprocess Performance				
GG 5	**Institutionalize an Optimizing Process**				
GP 5.1	Ensure Continuous Process Improvement				
GP 5.2	Correct Root Causes of Problems				

Table 2 - Mapping IEC 62304 to CMMI				
IEC 62304 Section	**Description**	**CMMI Component**	**Alignment Strength**	**Observations**
4	**General requirements**			
4.1	**Quality management system**	ALL	MODERATE	CMMI is the QMS, without a safety focus
4.2	**RISK MANAGEMENT**	RSKM	STRONG	
4.3	**Software safety classification**	RM RD	MODERATE MODERATE	CMMI does not address safety specifically
5	**Software development PROCESS**			
5.1	**Software development planning**			
5.1.1	**Software development plan**	PP SG2	STRONG	
5.1.2	**Keep software development plan updated**	PP GP 2.6 PP GP 2,8	STRONG MODERATE	
5.1.3	**Software development plan reference to SYSTEM design and development**	IPM SP 1.4	WEAK	SP 1.4 is much more, but references to other plans is a start
5.1.4	**Software development standards, methods and tools planning**	IPM SP 1.2	STRONG	But with no OPD, we're not sure how good these assets are
5.1.5	**Software integration and integration testing planning**	PI SG 1 PI GP 2.2	STRONG	
5.1.6	**Software VERIFICATION planning**	VER SG 1 VER GP 2.2	STRONG	
5.1.7	**Software RISK MANAGEMENT planning**	RSKM	STRONG	
5.1.8	**Documentation planning**	CM PP GP 2.6	STRONG	
5.1.9	**Software configuration management planning**	CM PP SP 2.3 PP GP 2.6	STRONG	
5.1.10	**Supporting items to be controlled**	CM PP GP 2.6	MODERATE	Not specifically addressed
5.1.11	**Software CONFIGURATION ITEM control before VERIFICATION**	CM SP 1.3	MODERATE	Timing is not specifically addressed in CMMI

Table 2 - Mapping IEC 62304 to CMMI				
IEC 62304 Section	**Description**	**CMMI Component**	**Alignment Strength**	**Observations**
5.2	**Software requirements analysis**			
5.2.1	**Define and document software requirements from SYSTEM requirements**	RD SG 2	STRONG	
5.2.2	**Software requirements content**	RD	MODERATE	Elements a-l not all addressed in CMMI
5.2.3	**Include RISK CONTROL measures in software requirements**	RSKM SG 3 RM SP 1.4	WEAK	Not specifically addressed in CMMI
5.2.4	**Re-EVALUATE MEDICAL DEVICE RISK ANALYSIS**	RSKM SP 3.2	STRONG	But Cohesion between mitigation activities and requirements not emphasized in CMMI
5.2.5	**Update SYSTEM requirements**	RM SP 1.4 CM SG 2 RD GP 2.8	STRONG	
5.2.6	**Verify software requirements**	RD SG 3 VER SG 2	STRONG	Specific criteria not defined in CMMI
5.3	**Software ARCHITECTURAL design**			
5.3.1	**Transform software requirements into an ARCHITECTURE**	TS SP 2.1	STRONG	
5.3.2	**Develop an ARCHITECTURE for the interfaces of SOFTWARE ITEMS**	TS SP 2.3	STRONG	
5.3.3	**Specify functional and performance requirements of SOUP item**	RD TS	MODERATE	SOUP not singled out in CMMI in this way
5.3.4	**Specify SYSTEM hardware and software required by SOUP item**	RD TS	MODERATE	SOUP not singled out in CMMI in this way
5.3.5	**Identify segregation necessary for RISK CONTROL**	RD	WEAK	Could be implemented in RD, but not specifically addressed in CMMI
5.3.6	**Verify software ARCHITECTURE**	VER SG 2,3 PI SP 2.1, 3.1	STRONG MODERATE	CMMI does not specifically call out SOUP
5.4	**Software detailed design**			
5.4.1	**Refine SOFTWARE ARCHITECTURE into SOFTWARE UNITS**	RD SG 2	STRONG	
5.4.2	**Develop detailed design for each SOFTWARE UNIT**	TS SG 2	STRONG	

Table 2 - Mapping IEC 62304 to CMMI				
IEC 62304 Section	**Description**	**CMMI Component**	**Alignment Strength**	**Observations**
5.4.3	**Develop detailed design for interfaces**	TS	STRONG	
5.4.4	**Verify detailed design**	PI SP 3.1 VER	STRONG	
5.5	**SOFTWARE UNIT implementation and verification**			
5.5.1	**Implement each SOFTWARE UNIT**	TS SP 3.1	STRONG	
5.5.2	**Establish SOFTWARE UNIT VERIFICATION PROCESS**	VER SG 1, 2	MODERATE	CMMI applies VER selectively. Verification of test procedures is done selectively in CMMI.
5.5.3	**SOFTWARE UNIT acceptance criteria**	PI SP 3.1 VER SP 1.3	STRONG	
5.5.4	**Additional SOFTWARE UNIT acceptance criteria**	VER SG 1,2	MODERATE	Criteria applies selectively in CMMI
5.5.5	**SOFTWARE UNIT VERIFICATION**	VER SG 3	STRONG	
5.6	**Software integration and integration testing**			
5.6.1	**Integrate SOFTWARE UNITS**	PI SP 3.2	STRONG	
5.6.2	**Verify software integration**	PI SP 3.3	MODERATE	CMMI does not address support for manual operations
5.6.3	**Test integrated software**	PI SP 3.3 VER SG 3	STRONG	
5.6.4	**Integration testing content**	VER SP 3.2	STRONG	
5.6.5	**Verify integration test procedures**	VER SG 2,3	MODERATE	Only selectively applied in CMMI
5.6.6	**Conduct regression tests**	PI SP 3.3 VER SG 2,3	MODERATE	Not specifically called out in CMMI, but inferred
5.6.7	**Integration test record contents**	PI SP 3.3 VER SG 3	MODERATE	Specific requirements not addressed in CMMI
5.6.8	**Use software problem resolution PROCESS**	CM SP 2.1	MODERATE	CMMI does not address problem resolution specifically
5.7	**SOFTWARE SYSTEM testing**			

Table 2 - Mapping IEC 62304 to CMMI				
IEC 62304 Section	**Description**	**CMMI Component**	**Alignment Strength**	**Observations**
5.7.1	**Establish tests for software requirements**	RM SP 1.4 VER SP 1.3	MODERATE	CMMI does not specifically require that ALL requirements are tested
5.7.2	**Use software problem resolution PROCESS**	CM SP 2.1	MODERATE	CMMI does not address problem resolution specifically
5.7.3	**Retest after changes**	PI SP 3.3 CM SG 2 VER SG 2,3	MODERATE	Not specifically called out in CMMI, but inferred
5.7.4	**Verify SOFTWARE SYSTEM testing**	VER	MODERATE	Specific requirements not stressed in CMMI
5.7.5	**SOFTWARE SYSTEM test record contents**	PI SP 3.3 VER SG 3	MODERATE	Specific requirements not addressed in CMMI
5.8	**Software release**			
5.8.1	**Ensure software VERIFICATION is complete**	VER SP 2.3 VER SP 3.2	STRONG	
5.8.2	**Document known residual ANOMALIES**	CM SP 2.1 VER SP 3.2	MODERATE	Not specifically addressed in CMMI
5.8.3	**EVALUATE known residual ANOMALIES**	RSKM SG 2 VER SP 3.2	MODERATE	Not specifically addressed in CMMI
5.8.4	**Document released VERSIONS**	PI SP 3.4 CM SP 1.3 CM SP 3.1	STRONG	
5.8.5	**Document how released software was created**	PI SG 1 CM SP 1.3 CM SP 3.1	STRONG	
5.8.6	**Ensure activities and tasks are complete**	PMC SP 1.7	STRONG	
5.8.7	**Archive software**	CM SP 1.3 CM SP 3.1	MODERATE	Specific archival requirements not addressed in CMMI
5.8.8	**Assure repeatability of software release**	CM SP 3.2 PPQA SG 1	STRONG	
6	**Software maintenance PROCESS**			
6.1	**Establish software maintenance plan**	PP SG 2	MODERATE	Maintenance is not specifically discussed in CMMI, but

Table 2 - Mapping IEC 62304 to CMMI				
IEC 62304 Section	**Description**	**CMMI Component**	**Alignment Strength**	**Observations**
		TS 2.2 TS 3.2		inferred
6.2	**Problem and modification analysis**			
6.2.1	**Document and EVALUATE feedback**			
6.2.1.1	**Monitor feedback**	CM SP 2.1	MODERATE	Not specifically addressed in CMMI
6.2.1.2	**Document and EVALUATE feedback**	CM SG 2	MODERATE	Not specifically addressed in CMMI
6.2.1.3	**Evaluate PROBLEM REPORT'S affects on SAFETY**	CM SG 2 RSKM SG 2	MODERATE	Not specifically addressed in CMMI
6.2.2	**Use software problem resolution PROCESS**	CM SP 2.1	MODERATE	Not specifically addressed in CMMI
6.2.3	**Analyze CHANGE REQUESTS**	CM SP 2.2	STRONG	
6.2.4	**CHANGE REQUEST approval**	CM SP 2.2	STRONG	
6.2.5	**Communicate to users and regulators**	CM SP 1.2	MODERATE	Specific reporting requirements not stressed in CMMI
6.3	**Modification implementation**			
6.3.1	**Use established PROCESS to implement modification**	CM GP 2.2	MODERATE	
6.3.2	**Re-release modified SOFTWARE SYSTEM**	PI SG 3 CM SP 1.3	MODERATE	Some elements of 5.8 are MODERATE
7	**Software RISK MANAGEMENT PROCESS**			
7.1	**Analysis of software contributing to hazardous situations**			
7.1.1	**Identify SOFTWARE ITEMS that could contribute to a hazardous situation**	RSKM SG2	MODERATE	Safety risk analysis not specifically required by CMMI
7.1.2	**Identify potential causes of contribution to a hazardous situation**	RSKM SP 1.1 RSKM SG 2	MODERATE	Safety risk analysis not specifically required by CMMI
7.1.3	**EVALUATE published SOUP ANOMALY lists**	RSKM SP 1.1	MODERATE	Not specifically required by CMMI
7.1.4	**Document potential causes**	RSKM SP 1.1 RSKM SG 2	MODERATE	Safety risk analysis not specifically required by CMMI

Table 2 - Mapping IEC 62304 to CMMI				
IEC 62304 Section	**Description**	**CMMI Component**	**Alignment Strength**	**Observations**
7.1.5	**Document sequences of events**	RSKM SG 1 RSKM SG 2	MODERATE	Not specifically required by CMMI
7.2	**RISK CONTROL measures**			
7.2.1	**Define RISK CONTROL measures**	RSKM SP 3.1	STRONG	
7.2.2	**RISK CONTROL measures implemented in software**	RSKM SP 2.1 RD SG 1, 2	MODERATE Not specifically required by CMMI
7.3	**VERIFICATION of RISK CONTROL measures**			
7.3.1	**Verify RISK CONTROL measures**	VER SG 2,3	MODERATE	CMMI applies VER selectively
7.3.2	**Document any new sequences of events**	RSKM SG 2	MODERATE	Not specifically required by CMMI
7.3.3	**Document TRACEABILITY**	RM SP 1.4	MODERATE	Risk traceability not specifically required by CMMI
7.4	**RISK MANAGEMENT of software changes**			
7.4.1	**Analyze changes to MEDICAL DEVICE SOFTWARE with respect to SAFETY**	CM SP 2.2	MODERATE	Not specifically required by CMMI
7.4.2	**Analyze impact of software changes on existing RISK CONTROL measures**	CM SP 2.2	MODERATE	Not specifically required by CMMI
7.4.3	**Perform RISK MANAGEMENT ACTIVITIES based on analyses**	CM SP 2.2	MODERATE	Not specifically required by CMMI
8	**Software configuration management PROCESS**			
8.1	**Configuration identification**			
8.1.1	**Establish means to identify CONFIGURATION ITEMS**	CM SP 1.1	STRONG	
8.1.2	**Identify SOUP**	CM SP 1.1		
8.1.3	**Identify SYSTEM configuration documentation**	CM SP 1.3	STRONG	
8.2	**Change control**			
8.2.1	**Approve CHANGE REQUESTS**	CM SP 1.2	STRONG	

Table 2 - Mapping IEC 62304 to CMMI				
IEC 62304 Section	**Description**	**CMMI Component**	**Alignment Strength**	**Observations**
		CM SP 2.2	STRONG	
8.2.2	**Implement changes**	CM SP 2.1 RSKM	STRONG STRONG	
8.2.3	**Verify changes**	CM SP 2.1 VER	MODERATE	Not specifically required by CMMI
8.2.4	**Provide means for TRACEABILITY of change**	CM SP 1.2 CM SP 2.1	STRONG STRONG	
8.3	**Configuration status accounting**	CM SP 3.1	STRONG	
9	**Software problem resolution PROCESS**			
9.1	**Prepare PROBLEM REPORTS**	CM SP 2.1	WEAK	
9.2	**Investigate the problem**	CM SP 1.1	WEAK	CR may be created in response to a PR
9.3	**Advise relevant parties**	CM SP 3.1	WEAK	
9.4	**Use change control process**	CM SP 1.2 CM SP 2.2	STRONG STRONG	
9.5	**Maintain records**	CM SP 3.1	STRONG	But addresses CRs not PRs
9.6	**Analyze problems for trends**	CM GP 2.8 CAR	WEAK	Only lightly addressed. CAR would imply quantitative management and a stable process.
9.7	**Verify software problem resolution**	CM SP1.1 VER SG 3	STRONG	
9.8	**Test documentation contents**	CM SP 1.1 VER SG 3	MODERATE	Not specifically required by CMMI