



Norm Traceability in System Configuration Management Context

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Services & Consulting

Migrations, Installation, Trainings, Extensions

Development

Custom Software development



5
Locations
Germany Switzerland, Czechia,
Slovakia, USA



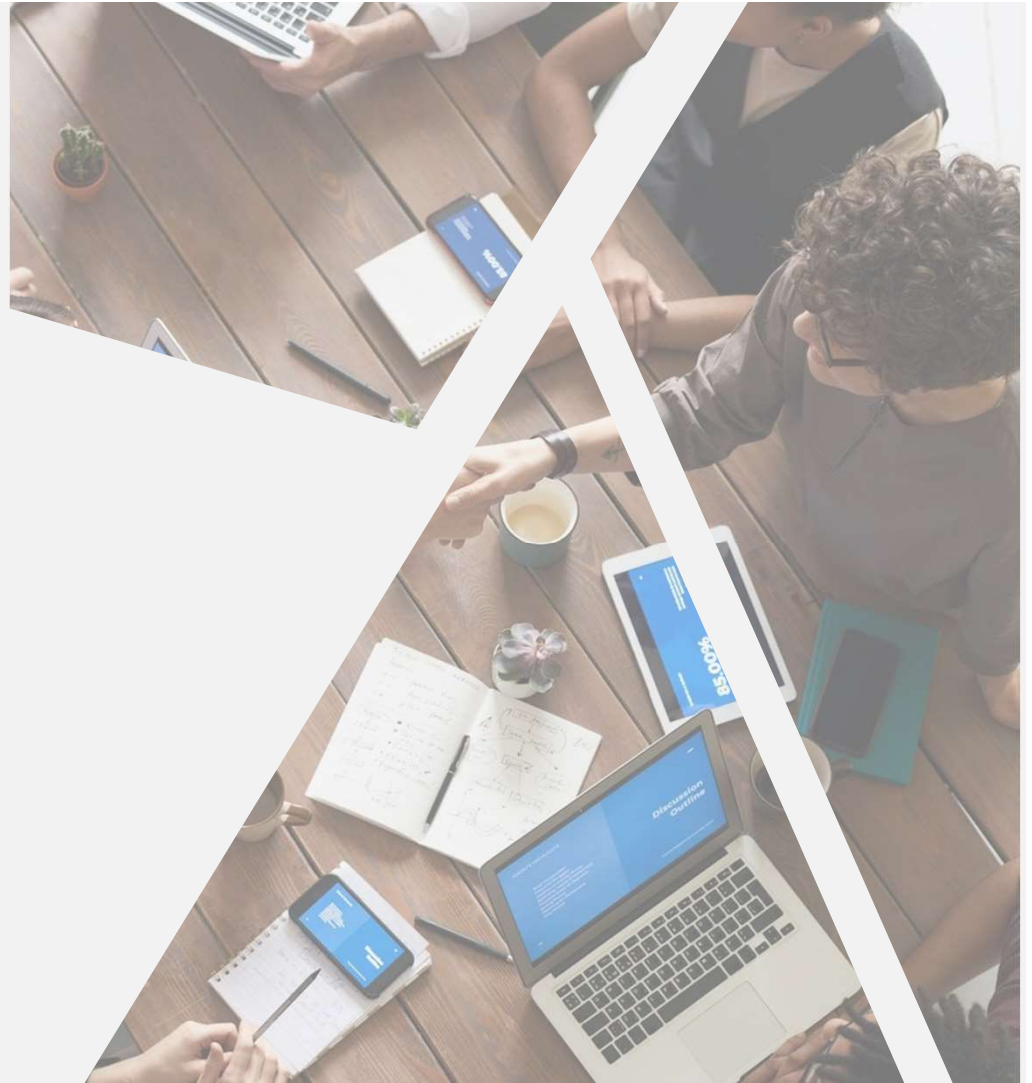
50+
employees



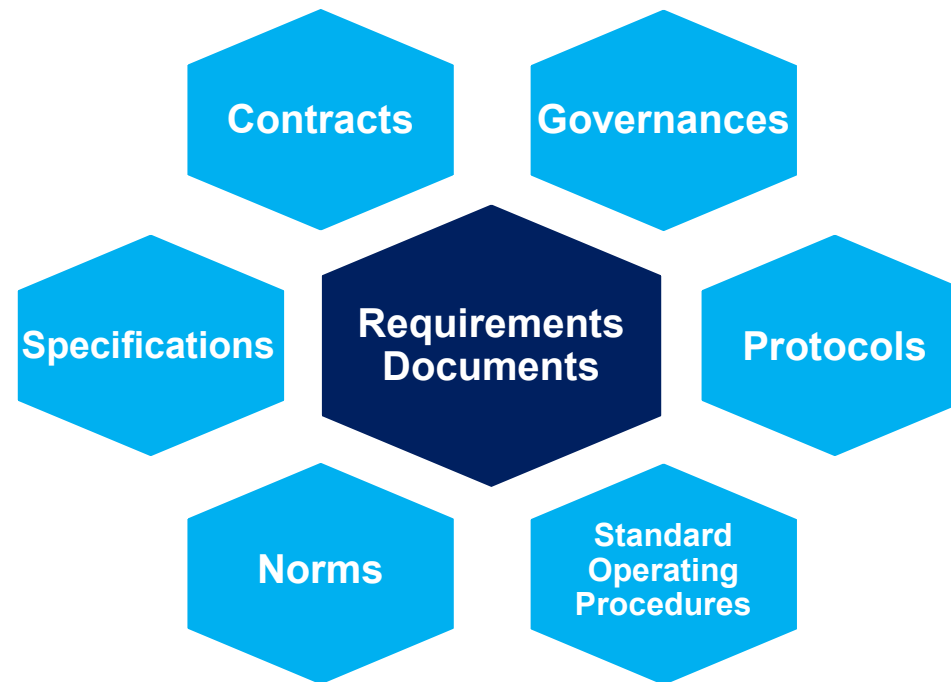
established in
1981



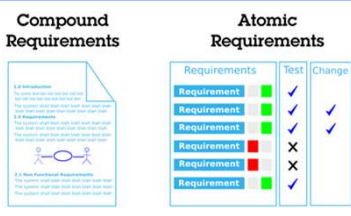
50+
worldwide projects
MedDev, Pharma, Automotive, A&D



Requirements management exists in many forms and in all projects



The 8 fundamentals that drive good Requirements & Norm Management




Compound Requirements **Atomic Requirements**

Requirements	Test	Change
Requirement	✓	✓
Requirement	✓	✓
Requirement	✗	✓
Requirement	✗	✗
Requirement	✓	✓

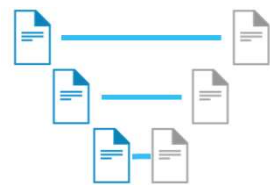
Granularity

Atomic
Testable
Manage changes




Attribute

Extend metadata
Search
Filter




Hierarchy

Organise & Structure
Decompose
Reduce complexity



Traceability

Bi-directional
Track changes
Suspect linking




Collaboration

Team visibility
Discuss and comment
Review



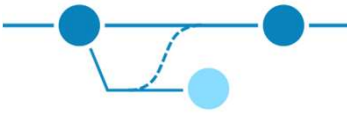
History/Security

Audit Trail
Who what and when
Secure



Reporting

Quality Publishing
Notifications
Dashboards



Configurations

Strategic Reuse
Versioning
Product Lines

Introduction to Requirements Interchange Format (ReqIF) and its importance

ReqIF is a standard format for exchanging requirements between different tools

ReqIF allows software tools from different vendors to exchange requirements and metadata while maintaining data integrity and defines a workflow for transmitting requirement status between partners.

Importance of ReqIF in ensuring seamless collaboration and data exchange in requirements engineering

ReqIF is an XML file format for lossless requirement exchange that replaces lossy methods like Office Documents, PDF or Spreadsheets.



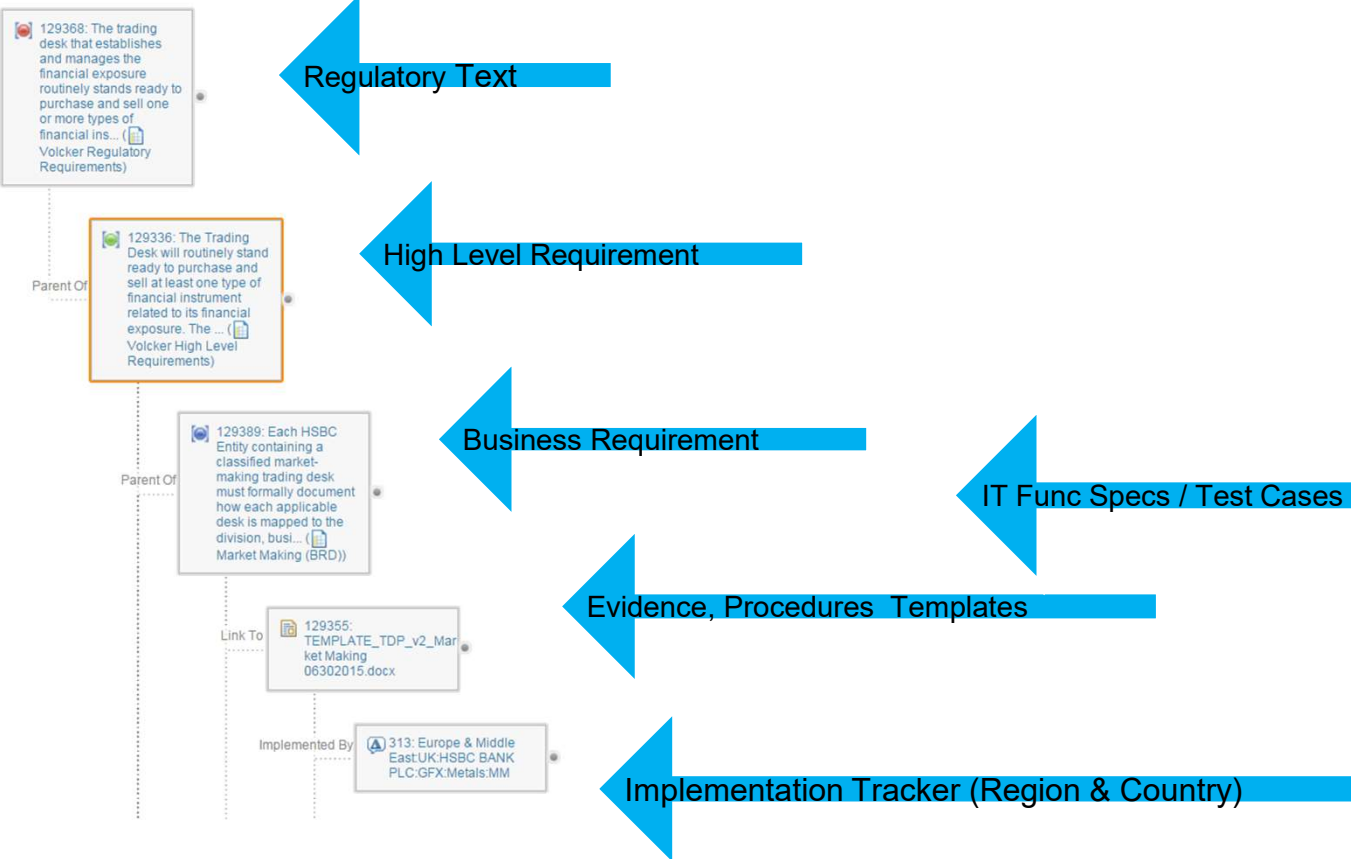
Regulatory Requirements imported

The screenshot displays the IBM Engineering Requirements Management (ERM) interface. The browser address bar shows a URL for a remote desktop connection. The application header includes navigation options like 'Norms', 'Project Dashboard', 'Artifacts', 'Reviews', and 'Reports'. The main content area is titled '6642 IEC 60601-1 - Medical electrical equipment - Part 1'. A table lists imported requirements with columns for ID, Contents, Project, Rationale, Notes, and Related Norm. The table contains several rows, with the last row (ID 6648) highlighted in orange. The 'Views' sidebar on the left shows 'Default view' selected.

ID	Contents	Project	Rationale	Notes	Related Norm
6643	-1 Scope and related standards				
6650	No content imported here.				
6644	-2 Terms and definitions				
6651	No content imported here.				
6645	-3 General requirements				
6646	SUPPLY MAINS in the HOME ENVIRONMENT shall be assumed to have the following characteristics: no voltage in excess of 110 % or lower than 85 % of the NOMINAL voltage between any of the conductors of the system or between any of these conductors and earth.				5015:The infusion pump shall be able to detect too much pressure in the delivery line. (In ...
6647	Unless otherwise indicated in the instructions for use or if the ME EQUIPMENT is STATIONARY, the ME EQUIPMENT shall remain operational in NORMAL USE within its specification and the requirements of this standard after transport or storage in the following environmental range: - 15 °C to +5 °C, and +5 °C to +37 °C at a relative humidity up to 90 %, non-condensing; >37 °C to 70 °C at a water vapor pressure up to 50 hPa after having been removed from its protective packaging and subsequently between uses.	Pump 1.0, Pump 1.1			4886:The pump channel shall deliver an infusion upon receipt of a "start infusion" command (... 6652:L_2017117EN.01000101.pdf
6648	If the INTERNAL ELECTRICAL POWER SOURCE is essential to maintain BASIC SAFETY or to maintain ESSENTIAL PERFORMANCE or control the RISKS associated with the loss of ESSENTIAL PERFORMANCE, the ME EQUIPMENT shall be equipped with a means for the OPERATOR to determine the state of the INTERNAL ELECTRICAL POWER SOURCE. The state of the INTERNAL ELECTRICAL POWER SOURCE may be indicated as: a number of PROCEDURES remaining, the remaining operating time, the percentage of the remaining operating time or energy, or a "fuel" gauge. The state of the INTERNAL ELECTRICAL POWER SOURCE may be indicated continuously or by OPERATOR action.	Pump 1.0	Some internal text going over several Lines	Required for products MEsDX34	5042:The infusion pump shall have a battery for backup power (In Module: Infusion Pump ... 4968:The system shall be allow patients to self-administer a controlled amount of medication,...



Assess the impact of change with the regulatory traceability explorer



Traceability can be extended across the whole project lifecycle including for example IT Functional Specs & Test Cases

Regulations to High Level Requirements Traceability

The screenshot displays the IBM Requirements Management interface for a 'Regulatory Change Portfolio (Requirements)'. The main table lists 19 artifacts, each representing a regulation and its associated business requirements. The table columns are: ID, Contents, Artifact Type, Trace A..., Business Requirements, and Parent Of.

ID	Contents	Artifact Type	Trace A...	Business Requirements	Parent Of
129369	I. Background	Regulation	NO	No requirement required	
129364	The Dodd-Frank Act was enacted on July 21, 2010. 1 Section 619 of the Dodd-Frank Act added a new section 13 to the Bank Holding Company Act of 1956 ('BHC Act') (codified at 12 U.S.C. 1851) that generally prohibits any banking entity from engaging in proprietary trading or from acquiring or retaining an ownership interest in, sponsoring, or having certain relationships with a hedge fund or private equity fund ('covered fund?'), subject to certain exemptions. 2 New section 13 of the BHC Act also provides that a nonbank financial company designated by the Financial Stability Oversight Council (FSOC?) for supervision by the Board (while not a banking entity under section 13 of the BHC Act) would be subject to additional capital requirements, quantitative limits, or other restrictions if the company engages in certain proprietary trading or covered fund activities. 3	Regulation	NO	No requirement required	129374: Subsequent requirements address the required elements of the Compliance Program within the context of each specific, identified aspect of that Compliance Program (Volcker High Level Requirements)
129352	Section 13 of the BHC Act generally prohibits banking entities from engaging as principal in proprietary trading for the purpose of selling financial instruments in the near term or otherwise with the intent to resell in order to profit from short-term price movements. 4 Section 13(d)(1) expressly exempts from this prohibition, subject to conditions, certain activities, including:	Regulation	NO	No requirement required	
129372	1 Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, 124 Stat. 1376 (2010).	Regulation	NO	No requirement required	
129376	2 See 12 U.S.C. 1851.	Regulation	NO	No requirement required	
129371	3 See 12 U.S.C. 1851(a)(2) and (f)(4). The Agencies note that two of the three companies currently designated by FSOC for supervision by the Board are affiliated with insured depository institutions, and are therefore currently banking entities for purposes of section 13 of the BHC Act. The Agencies are continuing to review whether the remaining company engages in any activity subject to section 13 of the BHC Act and what, if any, requirements apply under section 13.	Regulation	NO	No requirement required	
129375	Permitted market making-related activities. The prohibition contained in 11.3(a) does not apply to a banking entity's market making-related activities conducted in accordance with this paragraph (b).	Regulation	YES	Requirement written	129367: The Trading Desk will not engage in proprietary trading unless the trading activity meets the definition of Market Making-Related Activity. (Volcker High Level Requirements)
129368	The trading desk that establishes and manages the financial exposure routinely stands ready to purchase and sell one or more types of financial instruments related to its financial exposure and is willing and available to quote, purchase and sell, or otherwise enter into long and short positions in those types of financial instruments for its own account, in commercially reasonable amounts and throughout market cycles on a basis appropriate for the liquidity, maturity, and depth of the market for the relevant types of financial instruments;	Regulation	YES	Requirement written	129336: The Trading Desk will routinely stand ready to purchase and sell at least one type of financial instrument related to its financial exposure. The Trading Desk will be willing and available to quote, purchase, or sell long and short positions in [Financial Instrument] for its own account. A Trading Desk must be willing and available to Quote / Trade in commercially reasonable amounts on a basis appropriate for the liquidity, maturity, and depth of the market for the relevant types of financial instruments (Volcker High Level Requirements)
129363	The financial instruments each trading desk stands ready to purchase and sell in accordance with paragraph (b)(2)(i) of this section.	Regulation	YES	Requirement written	129374: Subsequent requirements address the required elements of the Compliance Program within the context of each specific, identified aspect of that Compliance Program (Volcker High Level Requirements)
129381	The actions the trading desk will take to demonstrably reduce or otherwise significantly mitigate promptly the risks of its financial exposure consistent with the limits required under paragraph (b).	Regulation	YES	Requirement written	129366: The Compliance Program must address the financial instruments each Trading Desk stands ready to purchase and

The interface includes a left-hand navigation pane with 'Views' and 'Filter by Tag' options. The IBM logo is visible in the bottom left corner, and a signature 'Jazz' is in the bottom right corner.

Regulations > High Level Requirement > Business Requirements

Regulatory Change Portfolio (Requirements) | Brad Middleton

Require... > Volcker > 10 - Regulations >

High Level Requirements

ID	Contents	Artifact Type	Parent Of
129379	129354: Definition of client, customer, and counterparty. For purposes of paragraph (b) of this section, the terms client, customer, and counterparty, on a collective or individual basis refer to market participants that make use of the banking entity's market making (Volcker Regulatory Requirements) Reg Ref: Subpart B (4) Section Ref: VRULE-5735 Artifact Type: Regulation	High Level Requirement	
129336	129368: The trading desk that establishes and manages the financial exposure routinely stands ready to purchase and sell one or more types of financial instruments related to its financial exposure and is willing and available to quote, purchase and sell, or other (Volcker Regulatory Requirements) Reg Ref: Subpart B (4) Section Ref: VRULE-5715 Artifact Type: Regulation	High Level Requirement	<ul style="list-style-type: none"> 129391: GBM must have a written policy to ensure that permitted market-making activities are designed not to violate the Backstop Prohibitions, as described in [ENTERPRISEWIDE BACKSTOP PROVISION POLICY] (Market Making (BRD)) ReqCategory: Market Making Req-Sub-Reference: Permitted Trading Process Category: Policy 129390: GBM and Group must consolidate the output of requirements MM_001.01 and MM_001.02, or a central repository must exist where master versions are stored for official use (Market Making (BRD)) ReqCategory: Market Making Req-Sub-Reference: Permitted Trading Process Category: Process 129388: GBM must formally identify and document those trading desks within an HSBC entity that will undertake permitted activity defined in and relying on the Market-Making Exemption (Market Making (BRD)) ReqCategory: Market Making Req-Sub-Reference: Permitted Trading Process Category: Procedure 129392: GBM must have a written policy that requires each market-making trading desk to maintain and conduct its activity in accordance with the written policies, procedures, and internal controls of the trading desk (Market Making (BRD)) ReqCategory: Market Making Req-Sub-Reference: Permitted Trading Process Category: Policy 129389: Each HSBC Entity containing a classified market-making trading desk must formally document how each applicable desk is mapped to the division, business line or other organisational structure responsible for managing and overseeing the desk's market-making (Market Making (BRD)) ReqCategory: Market Making Req-Sub-Reference: Permitted Trading Process Category: Procedure
129374	129364: The Dodd-Frank Act was enacted on July 21, 2010. Section 619 of the Dodd-Frank Act added a new section 13 to the Bank Holding Company Act of 1956 (BHC Act) (codified at 12 U.S.C. 1851) that generally prohibits any banking entity	High Level Requirement	

Showing 6 of 6 Artifacts

IBM Jazz

Business Requirements to Deliverables and Implementation Tracker

The screenshot displays the IBM Jazz Regulatory Change Portfolio (Requirements) interface. The main content is a table listing business requirements for Market Making (BRD). The table has columns for ID, Contents, BRD Requirement ID, Process Category, Referenced Rule, Country, Link To, Child Of, and Implemented By.

ID	Contents	BRD Requirement ID	Process Category	Referenced Rule	Country	Link To	Child Of	Implemented By
129387	A trading desk relying on the Market-Making Exemption must not engage in proprietary trading unless the trading activity meets the definition of market-making activity	MM_001	Header	N/A	N/A			
129388	GBM must formally identify and document those trading desks within an HSBC entity that will undertake permitted activity defined in and relying on the Market-Making Exemption	MM_001.01	Procedure	3.1 Volcker Rule Classificatic		129355:TEMPLATE_TDP_v2_Market Making 06302015.docx	129336: The Trading Desk will routinely stand ready to purchase and sell at least one type of financial instrument related to its financial exposure. The Trading Desk will be willing and available to quote, purchase, or sell long and short positions in [Financial Instrument] for its own account. A Trading Desk must be willing and available to Quote / Trade in commercially reasonable amounts on a basis appropriate for the liquidity, maturity, and depth of the market for the relevant types of financial instruments (Volcker High Level Requirements)	312: Europe & Middle East-UK-HSBC BANK PLC.GFX-FX Options-MM
129389	Each HSBC Entity containing a classified market-making trading desk must formally document how each applicable desk is mapped to the division, business line or other organisational structure responsible for managing and overseeing the desk's market-making activity	MM_001.02	Procedure	2.4 Reporting Line		129355:TEMPLATE_TDP_v2_Market Making 06302015.docx	129336: The Trading Desk will routinely stand ready to purchase and sell at least one type of financial instrument related to its financial exposure. The Trading Desk will be willing and available to quote, purchase, or sell long and short positions in [Financial Instrument] for its own account. A Trading Desk must be willing and available to Quote / Trade in commercially reasonable amounts on a basis appropriate for the liquidity, maturity, and depth of the market for the relevant types of financial instruments (Volcker High Level Requirements)	

The interface includes a left-hand navigation pane with options like 'Create New Business Requirement', 'Views', and 'Search Views'. The bottom status bar indicates 'Showing 48 of 48 Artifacts' and features the IBM logo and the name 'Jazz'.

Review version and validity of your requirements to ensure the right delivery

The screenshot shows a web application interface for Requirements Management. The main content area displays a list of requirements for the 'Automated Meter Reader' project. The requirements are organized into a tree structure with the following hierarchy:






- 373: AMR System Requirements Specification
 - 2 General Description
 - 2.1 Functions and Purpose
 - 2.2 Environmental Considerations
 - 3 System Requirement
 - 3.1 Functional Requirements
 - 3.1.1 Handheld device
 - 418: The handheld device shall provide for the means for the meter reader to manually enter a meter reading. (Medium Priority, Functional Requirement, Version 2)
 - 535: The handheld device shall interfaces with the city's backoffice software. (Low Priority, Functional Requirement, Beyond Version 2)
 - 435: The handheld device shall allow for programming of a defined route, advancing to the next meter on the route as the meter reader moves through the route. (Medium Priority, Functional Requirement, Version 2)
 - 545: The handheld device shall have the ability to search for accounts by Last Name, Service Address, Meter Number, and Unread Meters. (Medium Priority, Functional Requirement, Version 2)
 - 610: The handheld device shall have a screen capable of displaying the number of accounts that have been read.

Annotations in the image include:

- A blue cloud labeled "Requirement specification" pointing to the content of requirement 435.
- A blue cloud labeled "Indicate version and validity" pointing to the dropdown menu for requirement 435, which shows options: "Version 1", "Version 2", "Beyond Version 2", and "version 2".

ID	Contents	Priority	Requirement T...	Schedule
666	-2 General Description			
658	2.1 Functions and Purpose			
692	2.2 Environmental Considerations			
691	-3 System Requirement			
727	-3.1 Functional Requirements			
406	-3.1.1 Handheld device			
418	The handheld device shall provide for the means for the meter reader to manually enter a meter reading.	Medium	Functional	Version 2
535	The handheld device shall interfaces with the city's backoffice software.	Low	Functional	Beyond Version 2
435	The handheld device shall allow for programming of a defined route, advancing to the next meter on the route as the meter reader moves through the route.	Medium	Functional	Version 2
545	The handheld device shall have the ability to search for accounts by Last Name, Service Address, Meter Number, and Unread Meters.	Medium	Functional	Version 2
610	The handheld device shall have a screen capable of displaying the number of accounts that have been read.		Functional	version 2

Reduce the time needed to define requirements by reusing common norms

	ID	Contents	
<input type="checkbox"/>	126	The AMR system shall be able to operate in the market environments for which it is targeted and approved.	
<input type="checkbox"/>	67	Any portable equipment shall have an Ingress Protection Rating of IP66 or better in accordance with Standard IEC 60529.	
 <input type="checkbox"/> 	54	All portable equipment should survive multiple 6 ft./1.8 m drops on to concrete,	
<input type="checkbox"/>	95	In Modules (1)	
<input type="checkbox"/>	11	11 Requirements for Reuse	
<input type="checkbox"/>	168	<ul style="list-style-type: none">• Brazil• Canada• China• European Union• Japan• United States of America	
<input type="checkbox"/>	199	All portable equipment shall have Hazardous location certifications UL Class I, II, III Division II, A, B, C, D, F, G.	

Norms can be related /linked to many engineering domains

Requirements Management

IBM Engineering Requirements Management DOORS Next (J/rm)

Infusion Pump Requirements

Project Dashboard Artifacts Reviews Reports

... > 01 Stakeholder Requirements > | 4781 Infusion Pump Sta

Create View: 3. Satisfied By Type to filter artifacts by text or by ID

ID	Contents	Satisfied
4829	The device shall have a push button switch that will cycle through the available infusion methods.	
4952	The device shall emit a 80 dB tone when a button is depressed	
4897	The device shall allow a clinician to select one of six independent pump channels to program.	5037 pum Syst
4957	The device shall accept a delivery rate and total volume as parameters of a prescription.	
5046	The device shall allow a clinician to load a programmed prescription on the selected pump channel.	5049 com pres the p res Pum
4904	Each Pump Channel shall have a minimum and maximum delivery rate and total volume delivered.	4800 volu Syst 4801 rate Pum 4961 rate Pum
4830	The device fluid compartment shall be locked during Substance Delivery and Maintenance - Cleaning mode.	
4946	The device shall emit a 100 dB sound	

Ticketing System

IBM Engineering Workflow Management (J/ccm)

Infusion Pump Development

Project Dashboards Work Items Plans Source Control Builds Reports Des

Work Items > Queries (New Query) >

Change Request 396

Summary: Increase Max Pump Channel Rate to 10 Units Per Minute

Overview Impact Analysis Impact Assessment Summary Links

Details

Type: Change Request Owned By:

Type description: Sep 24, 2020, 3:02:13 PM Planned For:

Creation Date: Pete Due Date:

Created By: Priority: Medium Tags:

How Found: Internal

Filed Against: Solution Name (rename)

Change Description

Discussion

Add a comment...

Test Management

IBM Engineering Test Management (J/qm)

Infusion Pump Testing

Project Dashboards Requirements Planning Construction Lab Management Builds Execution

Test Cases >

You do not have permissions to edit. show details

109: Each pump channel shall have a maximum rate of 5 units per minute.

Test Case

Sections

- Summary
- Test Case Design
- Formal Review
- Development Items
- Requirement Links
- Risk Assessment
- Pre-Condition
- Post-Condition
- Expected Results
- Test Scripts
- Test Case Execution Records
- Attachments
- Execution Variables

State: Draft

Originator: Tony Owner: Unassigned

Priority: Unassigned

Description:

Requirement Links

View the requirements that are in a requirements management tool that integrate with Test Management by using OSLC; for example, IBM Engineering Requirements Management. For other types of requirements, see the Requirements section.

Group By: Ungrouped Type filter

Number of Items Per Page: Show All Previous | 1 - 1 of 1 | Next

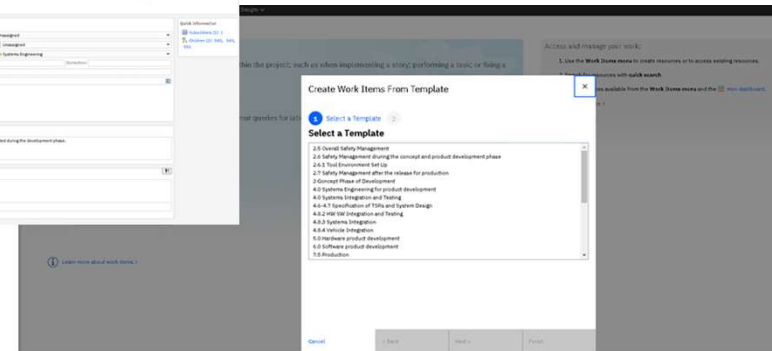
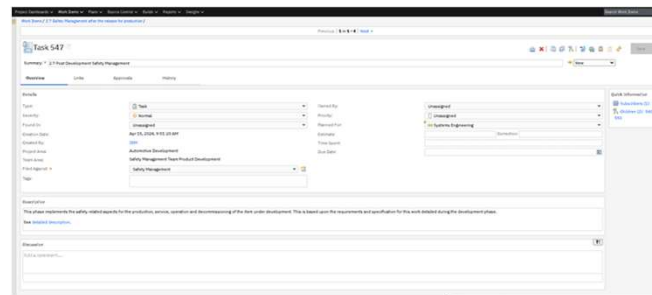
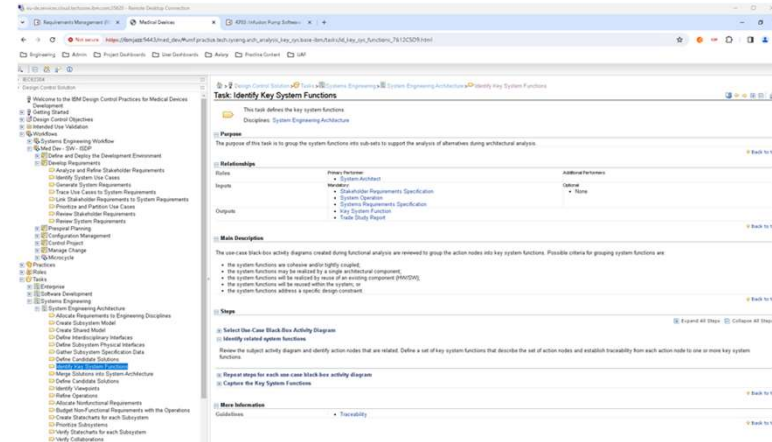
Suspect Contributor	Summary
	4964: Each pump channel st

Previous | 1 - 1 of 1 | Next

Linking to a Process according to Norm

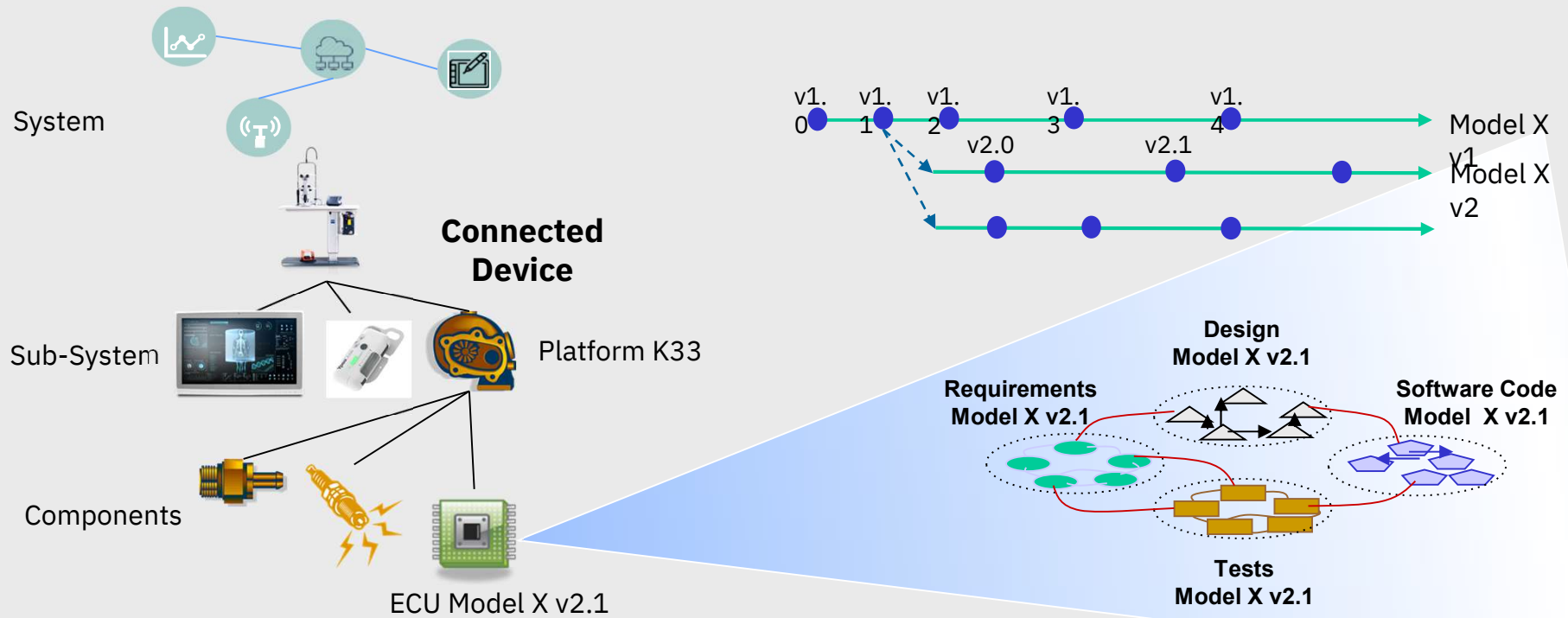
Generation of Work Items links to process

Proof of the correct process step implementation



Manage Complexity and Reuse

Keep all Engineering Artifacts under Version Control



Compare Norms

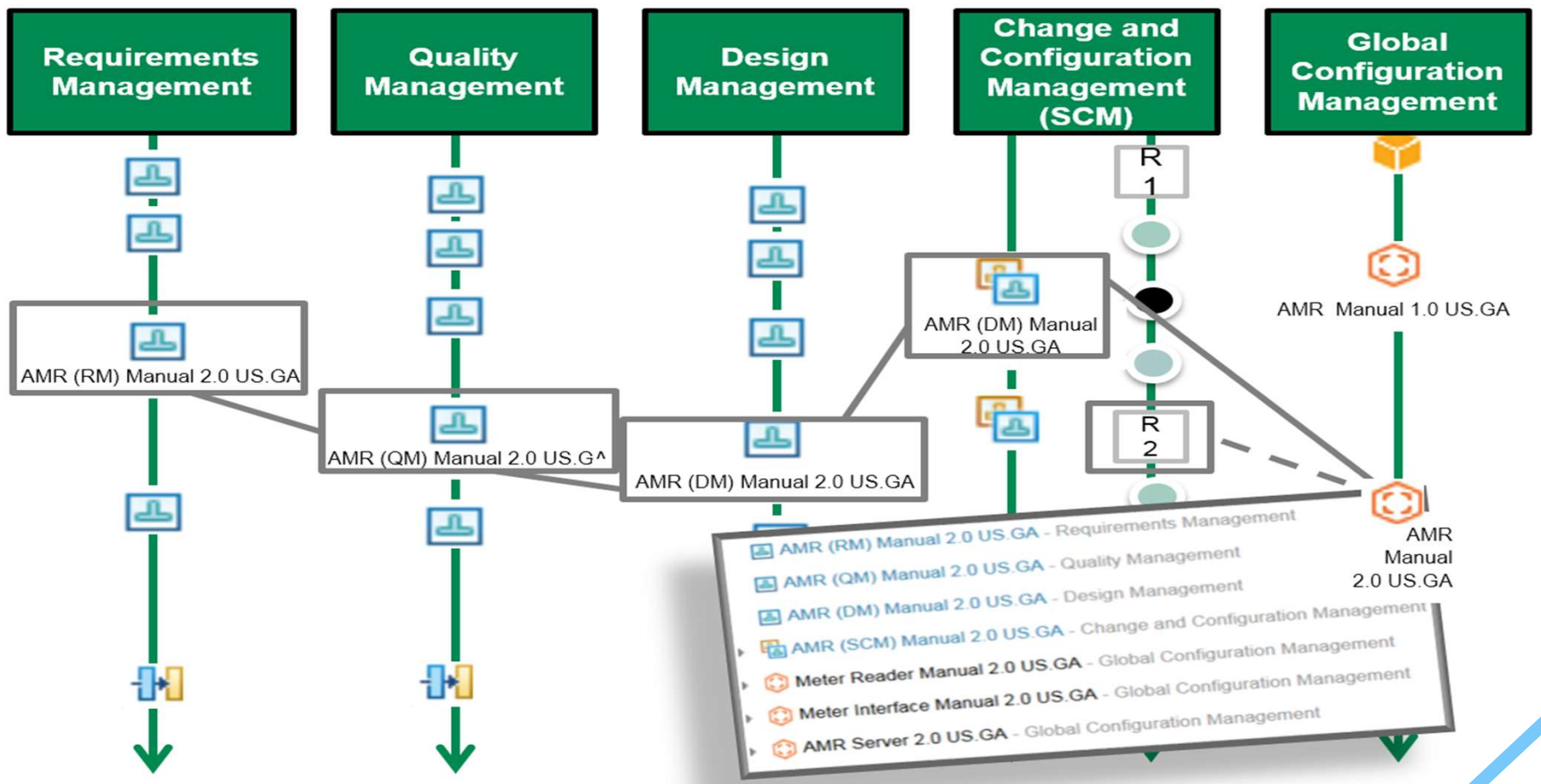
- ✓ Innovate faster through Reuse: Evolve your design instead of reinventing the wheel over and over.
- ✓ Introduce efficiency with agile practices: effectively orchestrate agile practices across teams with complete support for agile planning and tracking
- ✓ Early verification with model-based design: Leverage design model to virtually optimize and verify product architecture before committing to implementation

The screenshot displays the IBM Engineering Requirements Management DOORS Next (r/m) interface. The main window is titled "Compare Configurations" and shows a comparison between two versions of the "Infusion Pump System Requirements": "Infusion Pump Requirements Initial Stream (Source)" and "Infusion Master 2000 RC1 (Target)".

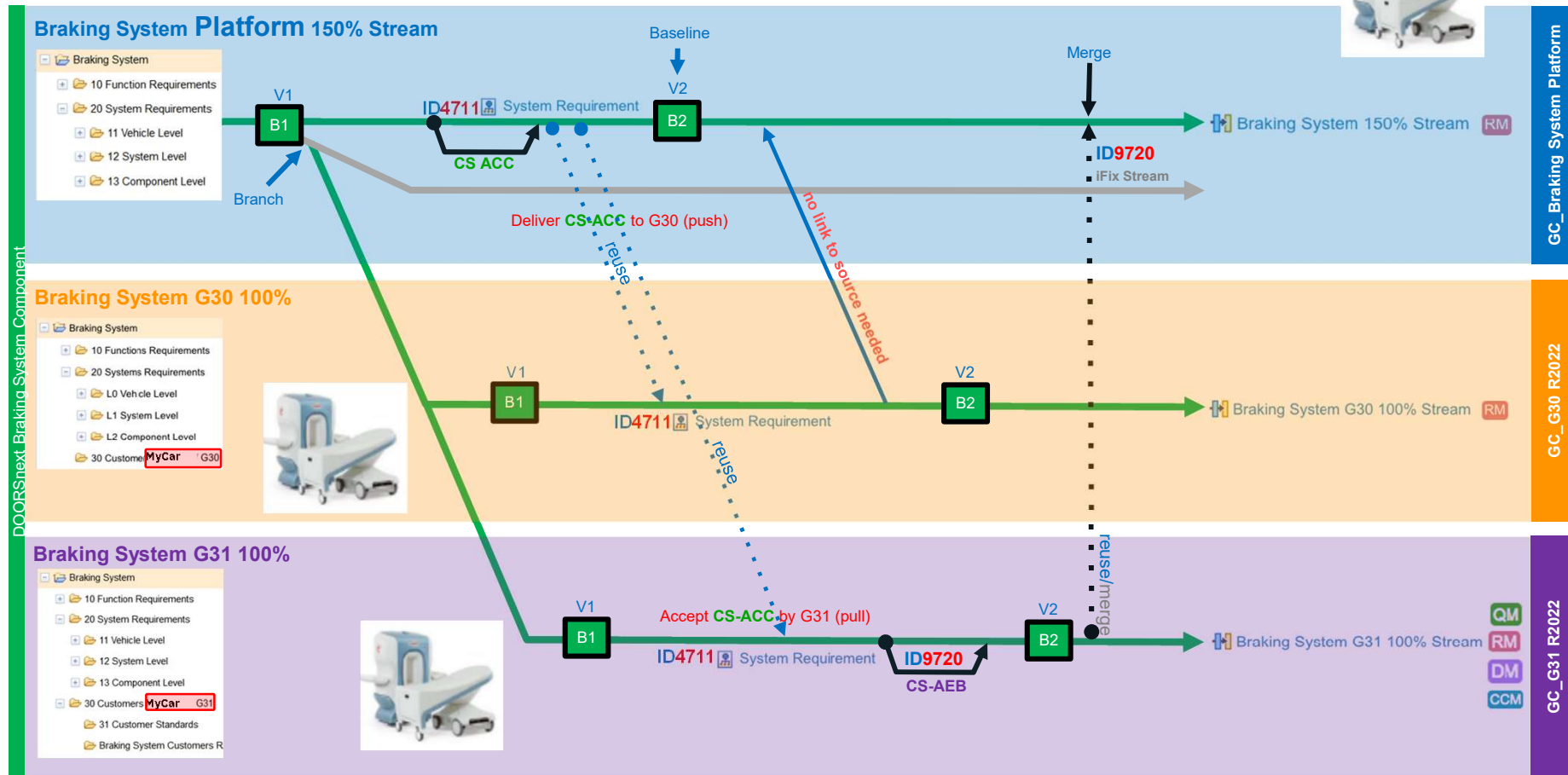
The interface is divided into several sections:

- Artifacts:** A list of artifacts on the left, including "4777: Infusion Pump System Requirements" and "4777: Infusion Pump System Requirements".
- Changes from Infusion Pump Requirements Initial Stream to Infusion Master 2000 RC1:** A table showing the differences between the two versions. The table has columns for "Content" and "Attributes".
- 1.1 Operating Modes:** A flowchart diagram showing the operational flow of the system, including states like "Start", "Self-Diagnostics", "Normal operation", "Turn Off", "Power-On", "Error Found", and "Error Resolved".
- 1.2 Functional Requirements:** A list of functional requirements, such as "The pump channel shall deliver an infusion upon receipt of a 'start infusion' command only when the pump channel has been armed and contains a valid prescription." and "The system shall allow drug infusion in any one of the three modes of infusions: Basal, square bolus and patient bolus."

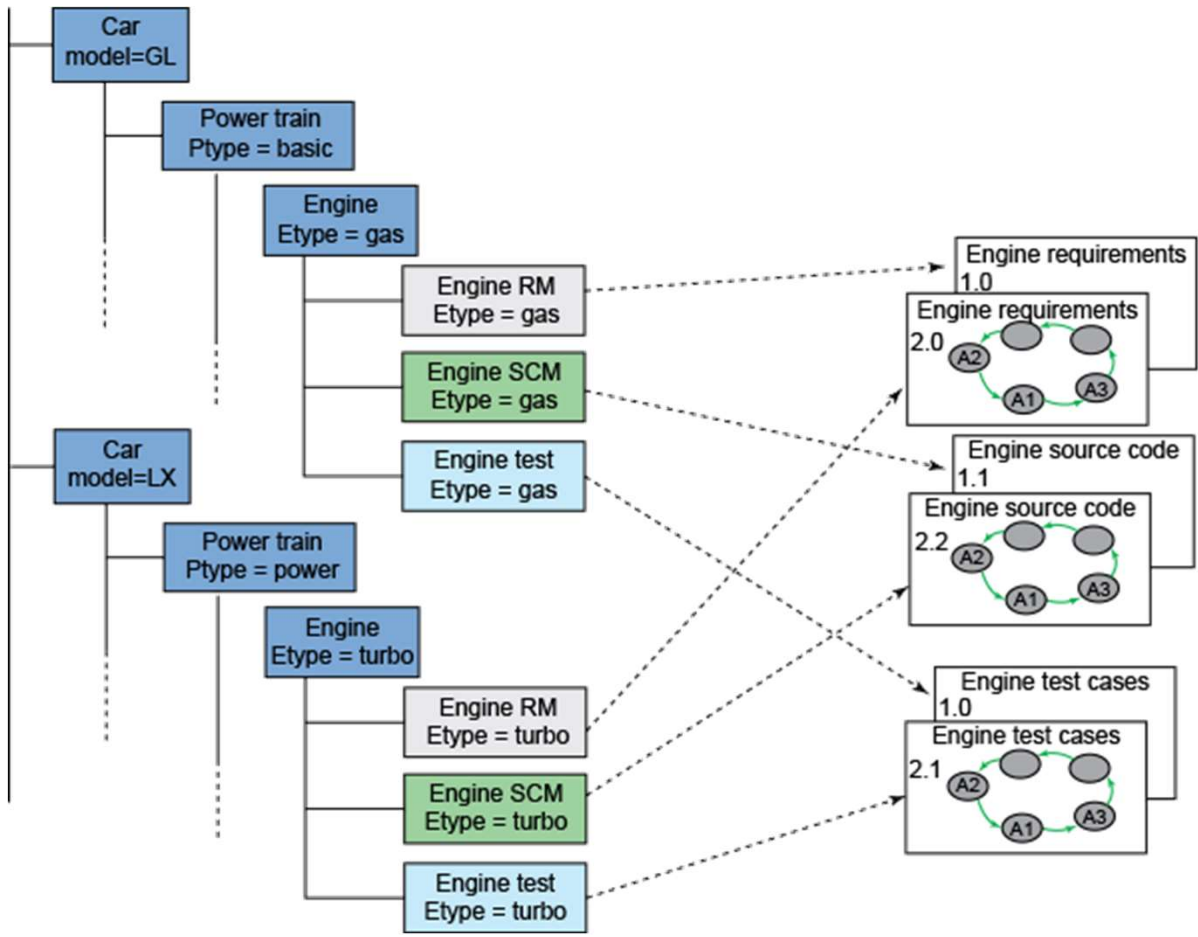
Global Configuration Management



Global Configuration Example of Specifications Reuse



Global Configurations Example



- Vehicle
 - Vehicle Requirements RM
 - Vehicle Test Plans and Cases QM
 - Drive Chain
 - Wheels
 - Tire Pressure Monitor
 - Tire Pressure Monitor Requirements Nov 2017 RM
 - Tire Pressure Monitor Test Plans Nov 2017 QM
 - Air Pressure Sensor
 - Air Pressure Sensor Requirements RM
 - Air Pressure Sensor Designs AM
 - Air Pressure Sensor Test Cases QM
- Engine
 - Engine Requirements RM
 - Engine Test Plans and Cases QM
 - Ignition System ECU
 - Ignition System ECU Requirements RM
 - Ignition System ECU Test Plans and Cases QM
 - Ignition System ECU Firmware CCM



Key lessons learned / project risks

Inefficient Traceability and Documentation management

- Inefficiencies created by sending emails to request data, organising and attending update meetings and making follow-up phone calls.
- Manual management of traceability data is difficult and error-prone with difficulties in immediately pointing out what was missing and to reconstruct End-2-End regulatory compliance.
- Difficult to maintain an audit trail of decisions.
- Managing versions and revisions of artifacts manually is challenging and error-prone.

Reporting

- Difficult to Obtain
 - Information can be distributed across multiple share points, geographies, spreadsheets and difficult to collate.
- Unreliable and Costly
 - Reporting is sometimes erroneous, incomplete or obsolete as a result of consolidation errors and delays.
 - Consolidated manual report had limited scope for real time analysis or historical audit
 - Costs were incurred maintaining teams of individuals to collate, analyze and document reporting data.

Ownership and execution tracking

- Difficult to identify and track documents statuses and ownerships.
- Manual processes required to assign and track progress on Project artifacts.



A word cloud of project-related terms in various shades of blue. The most prominent words are 'artifacts', 'documents', 'management', 'requirements', 'data', 'collate', 'difficult', 'reporting', 'information', 'manual', 'project', 'traceability', 'track', 'update', 'error', 'collaborative', 'business', 'audit', 'assign', 'costs', 'create', 'decision', 'compliance', 'consolidated', 'distributed', 'drill-down', 'due', 'emails', 'graphical', 'hubc', 'maintain', 'meetings', 'obsolete', 'ownership', 'phone', 'points', 'portfolio', 'presentation', 'prone', 'provided', 'real', 'request', 'result', 'slide', 'statuses', 'tool', 'trace', and 'update'.



THANK YOU