Business Management System: Requirements

00-BMS-002

Preface

This document defines the applicability of International Standards requirements to the Business Management System (BMS) processes implemented at GM Nameplate (GMN). The sources of these requirements include:

- **ISO 9001:2015;** Quality Management Systems – Requirements.
- **AS 9100D:2016;** Quality Management Systems – Requirements for Aviation, Space, and Defense Organizations.
- **ISO 13485:2016;** Medical devices – Quality management systems – Requirements for regulatory purposes.

These requirements are identified by clause and sub-clause. The application of each clause or sub-clause to a process, document, or other documentation is identified by a "**x**" or a "**n/a**".

- A clause or sub-clause applies where indicated by a "**x**".
- A clause or sub-clause does not apply where indicated by a "**n/a**".

Many of the requirements apply to more than one process or document. The following matrices reflects the primary reference that is most relevant to the standards requirement.

This document is to be used to bridge the Business Management System (BMS): Manual, 00-BMS-001 to the Business Management System (BMS): Procedures, 00-BMS-003 documents.

Standard requirements		GMN Documentation																
			BMS Processes															
ISO 9001: 2015	AS 9100D	BMS Manual	RFQ/Quotation	Order Processing	APQP	Manufacturing	Inspection and Packaging	Audit and Ship	Dispositioning NC Product	Document Control	Audits	Management Planning and Review	Hiring	Training	Calibration	Receiving Inspection	Purchasing	Work Instructions
4.1	4.1	x																
4.2	4.2	x																
4.3	4.3	x																
4.4	4.4	x																
5.1	5.1	x																
5.1.1	5.1.1	x																
5.1.2	5.1.2	x																
5.2	5.2	x																
5.2.1	5.2.1	x																
5.2.2	5.2.2	x																
5.3	5.3	x																
6.1	6.1											x						
6.2	6.2											x						
6.3	6.3											x						
7.1	7.1											x						
7.1.1	7.1.1											x						
7.1.2	7.1.2												x					
7.1.3	7.1.3											x						
7.1.4	7.1.4																	x
7.1.5	7.1.5														x			
7.1.6	7.1.6													x				
7.2	7.2													x				
7.3	7.3													x				
7.4	7.4											x		x				
7.5	7.5									x								
7.5.1	7.5.1									x								
7.5.2	7.5.2									x								
7.5.3	7.5.3									x								
8.1	8.1			x														
	8.1.1				x													
	8.1.2			x														
	8.1.3	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
	8.1.4					x												
8.2	8.2	x																
8.2.1	8.2.1	x																
8.2.2	8.2.2	x																
8.2.3	8.2.3		x															
8.2.4	8.2.4		x															

Standard requirements		GMN Documentation																
			BMS Processes															
ISO 9001: 2015	AS 9100D	BMS Manual	RFQ/Quotation	Order Processing	APQP	Manufacturing	Inspection and Packaging	Audit and Ship	Dispositioning NC Product	Document Control	Audits	Management Planning and Review	Hiring	Training	Calibration	Receiving Inspection	Purchasing	Work Instructions
8.3	8.3	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
8.3.1	8.3.1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
8.3.2	8.3.2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
8.3.3	8.3.3	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
8.3.4	8.3.4	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
8.3.5	8.3.5	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
8.3.6	8.3.6	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
8.4	8.4																x	
8.4.1	8.4.1																x	
8.4.2	8.4.2																x	
8.4.3	8.4.3																x	
8.5	8.5					x	x	x								x		
8.5.1	8.5.1					x	x	x								x		
	8.5.1.1																	x
	8.5.1.2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
	8.5.1.3						x											
8.5.2	8.5.2					x	x	x								x		
8.5.3	8.5.3					x	x									x		
8.5.4	8.5.4					x	x	x								x		
8.5.5	8.5.5			x	x													
8.5.6	8.5.6																	x
8.6	8.6							x										
8.7	8.7					x	x	x	x									
9.1	9.1											x						
9.1.1	9.1.1											x						
9.1.2	9.1.2											x						
9.1.3	9.1.3											x						
9.2	9.2										x							
9.3	9.3											x						
9.3.1	9.3.1											x						
9.3.2	9.3.2											x						
9.3.3	9.3.3											x						
10.1	10.1											x						
10.2	10.2																	x
10.3	10.3											x						

Standard requirements	GMN Documentation																
ISO 13485:2016	BMS Manual	*BMS Processes*															Work Instructions
		RFQ/Quotation	Order Processing	APQP	Manufacturing	Inspection and Packaging	Audit and Ship	Dispositioning NC Product	Document Control	Audits	Management Planning and Review	Hiring	Training	Calibration	Receiving Inspection	Purchasing	
4.1	x																
4.2	x																
4.2.1	x																
4.2.2	x																
4.2.3	x																
4.2.4									x								
4.2.5																	x
5.1											x						
5.2											x						
5.3											x						
5.4											x						
5.4.1											x						
5.4.2											x						
5.5											x						
5.5.1											x						
5.5.2											x						
5.5.3											x						
5.6											x						
5.6.1											x						
5.6.2											x						
5.6.3											x						
6.1											x						
6.2																	x
6.3											x						
6.4																	x
6.4.1																	x
6.4.2																	x
7.1			x	x													
7.2.1		x															
7.2.2			x	x													
7.2.3		x	x	x													
7.3	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
7.3.1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
7.3.2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
7.3.3	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
7.3.4	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
7.3.5	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a

Standard requirements	GMN Documentation															
ISO 13485:2016	BMS Manual	*BMS Processes*														Work Instructions
		RFQ/Quotation	Order Processing	APQP	Manufacturing	Inspection and Packaging	Audit and Ship	Dispositioning NC Product	Document Control	Audits	Management Planning and Review	Hiring	Training	Calibration	Receiving Inspection	Purchasing	
7.3.6	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
7.3.7	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
7.3.8	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
7.3.9	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
7.3.10	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
7.4.1																x	
7.4.2																x	
7.4.3																x	
7.5.1					x	x	x										
7.5.2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
7.5.3	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
7.5.4	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
7.5.5	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
7.5.6	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
7.5.7	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
7.5.8					x	x	x								x		
7.5.9.1					x	x	x								x	x	
7.5.9.2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
7.5.10																	x
7.5.11					x	x	x								x	x	
7.6														x			
8.1											x						
8.2.1											x						
8.2.2																	x
8.2.3																	x
8.2.4										x							
8.2.5											x						
8.2.6					x	x	x								x		
8.3.1								x									
8.3.2					x	x	x										
8.3.3								x									
8.3.4																	x
8.4											x						
8.5.1											x						
8.5.2																	x
8.5.3																	x

Standard		Clause
ISO 9001: 2015	AS 9100D	
4.1	4.1	Understanding the organization and its context
4.2	4.2	Understanding the needs and expectations of interested parties
4.3	4.3	Determining the scope of the quality management system
4.4	4.4	Quality management system and its processes
5.1	5.1	Leadership and commitment
5.1.1	5.1.1	General
5.1.2	5.1.2	Customer focus
5.2	5.2	Policy
5.2.1	5.2.1	Establishing the quality policy
5.2.2	5.2.2	Communicating the quality policy
5.3	5.3	Organizational roles, responsibilties, and authorities
6.1	6.1	Actions to address risks and opportunities
6.2	6.2	Quality objectives and planning to achieve them
6.3	6.3	Planning of changes
7.1	7.1	Resources
7.1.1	7.1.1	General
7.1.2	7.1.2	People
7.1.3	7.1.3	Infrastructure
7.1.4	7.1.4	Environment for the operation of processes
7.1.5	7.1.5	Monitoring and measuring resources
7.1.6	7.1.6	Organizational knowledge
7.2	7.2	Competence
7.3	7.3	Awareness
7.4	7.4	Communication
7.5	7.5	Documented information
7.5.1	7.5.1	General
7.5.2	7.5.2	Creating and updating
7.5.3	7.5.3	Control of documented information
8.1	8.1	Operational planning and control
	8.1.1	Operational risk management
	8.1.2	Configuration management
	8.1.3	Product safety
	8.1.4	Prevention of counterfeit parts
8.2	8.2	Requirements for products and services
8.2.1	8.2.1	Customer communication
8.2.2	8.2.2	Determining the requirements for products and services
8.2.3	8.2.3	Review of the requirements for products and services
8.2.4	8.2.4	Changes to requirements for products and services
8.3	8.3	Design and development of products and services
8.3.1	8.3.1	General
8.3.2	8.3.2	Design and development planning
8.3.3	8.3.3	Design and development inputs
8.3.4	8.3.4	Design and development controls
8.3.5	8.3.5	Design and development outputs
8.3.6	8.3.6	Design and development changes
8.4	8.4	Control of externally provdied processes, products and services
8.4.1	8.4.1	General
8.4.2	8.4.2	Type and extent of control
8.4.3	8.4.3	Information for external providers

Standard		Clause
ISO 9001: 2015	AS 9100D	
8.5	8.5	Production and service provision
8.5.1	8.5.1	Control of production and service provision
	8.5.1.1	Control of equipment, tools, and software programs
	8.5.1.2	Validation and control of special processes
	8.5.1.3	Production process verification
8.5.2	8.5.2	Identification and traceability
8.5.3	8.5.3	Property belonging to customers and external providers
8.5.4	8.5.4	Preservation
8.5.5	8.5.5	Post-delivery activities
8.5.6	8.5.6	Control of changes
8.6	8.6	Release of products and services
8.7	8.7	Control of nonconforming outputs
9.1	9.1	Monitorying, measurement, analysis, and evaluation
9.1.1	9.1.1	General
9.1.2	9.1.2	Customer satisfaction
9.1.3	9.1.3	Analysis and evaluation
9.2	9.2	Internal audit
9.3	9.3	Management review
9.3.1	9.3.1	General
9.3.2	9.3.2	Management review inputs
9.3.3	9.3.3	Management review outputs
10.1	10.1	General
10.2	10.2	Nonconformity and corrective action
10.3	10.3	Continual improvement

Standard ISO 13485:2016	Clause
4.1	General requirements
4.2	Documentation requirements
4.2.1	General
4.2.2	Quality manual
4.2.3	Medical device file
4.2.4	Control of documents
4.2.5	Control of records
5.1	Management commitment
5.2	Customer focus
5.3	Quality policy
5.4	Planning
5.4.1	Quality objectives
5.4.2	Quality management system planning
5.5	Responsibility, authority and communication
5.5.1	Responsibiltiy and authority
5.5.2	Management representative
5.5.3	Internal communication
5.6	Management review
5.6.1	General
5.6.2	Review input
5.6.3	Review output
6.1	Provision of resources
6.2	Human resources
6.3	Infrastructure
6.4	Work environment and contamination control
6.4.1	Work environment
6.4.2	Contamination control
7.1	Planning of product realization
7.2.1	Determination of requirements related to product
7.2.2	Review of requirements related to product
7.2.3	Communication
7.3	Design and development
7.3.1	General
7.3.2	Design and development planning
7.3.3	Design and development inputs
7.3.4	Design and development outputs
7.3.5	Design and development review
7.3.6	Design and development verification
7.3.7	Design and development validation
7.3.8	Design and development transfer
7.3.9	Control of design and development changes
7.3.10	Design and development files
7.4.1	Purchasing process
7.4.2	Purchasing information
7.4.3	Verification of purchased product
7.5.1	Control of production and service provision
7.5.2	Cleanliness of product
7.5.3	Installation activities
7.5.4	Servicing activities

Standard ISO 13485:2016	Clause
7.5.5	Particular requirements for sterile medical devices
7.5.6	Validation of processes for production and service provision
7.5.7	Particular requirements for validation of processes for sterilization and sterile barrier systems
7.5.8	Identification
7.5.9.1	General
7.5.9.2	Particular requirements for implantable medical devices
7.5.10	Customer property
7.5.11	Preservation of product
7.6	Control of monitoring and measuring equipment
8.1	General
8.2.1	Feedback
8.2.2	Complaint handling
8.2.3	Reporting to regulatory authorities
8.2.4	Internal audit
8.2.5	Monitoring and measurement of processes
8.2.6	Monitoring and measurment of product
8.3.1	General
8.3.2	Actions in response to nonconforming product detected before delivery
8.3.3	Actions in response to nonconforming product detected after delivery
8.3.4	Rework
8.4	Analysis of data
8.5.1	General
8.5.2	Corrective action
8.5.3	Preventive action