

New Product Introduction Checklist

D01

LN	Category	Link	Notes
1	Design documentation		
1.1	Procedures	BMS Structure Project 123	
1.2	Input, specification	BMS Structure Project 123	
1.3	Design risk assessment	BMS Structure Project 123	
1.4	Feasibility study	BMS Structure Project 123	
1.5	Project plan	BMS Structure Project 123	
1.6	Design review records	BMS Structure Project 123	
1.7	Lab. Notebooks	BMS Structure Project 123	
1.8	Product FMEA	BMS Structure Project 123	
1.9	Regulatory requirements and compliance	BMS Structure Project 123	
1.10	Verification	NA	Design review 8/12/24
1.11	Design output	BMS Structure Project 123	
1.12	Final prototype	BMS Structure Project 123	
1.13	Validation	BMS Structure Project 123	
1.14	Corrective actions, Action lists	BMS Structure Project 123	
1.15	Process FMEA	BMS Structure Project 123	
1.16	NPI plan	BMS Structure Project 123	
2	Production documentation		
2.1	Bill of materials (BoM)	SAP	
2.2	Job traveler	SAP	
2.3	Outsourced operations	BMS Structure Project 123	
2.4	Production procedures and work instructions	BMS Structure Project 123	
2.5	Receiving inspection specifications	BMS Structure Project 123	
2.6	Product identification, labeling	BMS Structure Project 123	
2.7	Traceably requirements	BMS Structure Project 123	

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2.8	In-process inspection instructions	BMS Structure Project 123	
2.9	Final inspection equipment, instructions	BMS Structure Project 123	
2.10	Deviations and non-conformities process	BMS Structure Project 123	
2.11	Pilot run 1	BMS Structure Project 123	
2.12	Pilot run 2	BMS Structure Project 123	
3	Process control		
3.1	Equipment installation qualification (IQ)	BMS Structure Project 123	
3.2	Equipment operational qualification (OQ)	BMS Structure Project 123	
3.3	Equipment performance qualification (PQ)	BMS Structure Project 123	
3.4	Equipment calibration and PM	Business PM System	Cal and PM software
3.5	Equipment operation documentation	BMS Structure Project 123	
4	Packaging and shipping		
4.1	Packaging procedures and work instructions	BMS Structure Project 123	
4.3	Labeling	BMS Structure Project 123	
3.3	Shipping conditions validation	BMS Structure Project 123	
5	Personnel		
5.1	Personnel qualifications requirements	Business LMS	Learning Management Syst.
5.2	Personnel training requirements	Business LMS	
5.3	Training materials	Business LMS	
5.4	Training records maintenance	Business LMS	
6	Supply chain		
6.1	Supplier evaluation procedure	BMS Structure	

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6.2	Supplier evaluation records	BMS Structure	
6.3	Supplier Agreements	BMS Structure	
6.4	Back-up suppliers	BMS Structure	
6.5	Inventory availability	SAP	
7	Software		
7.1	IT software documentation	BMS Structure	
7.2	Contingency plan	BMS Structure	
7.3	Data back-up procedure	BMS Structure	
7.4	Process software validation	BMS Structure	
7.5	Production software validation	BMS Structure	
7.6	Product software loading work instructions	BMS Structure Project 123	
8	Infrastructure		
8.1	Production facilities documentation	BMS Structure	
8.2	Utilities: electrical: IQ, OQ	BMS Structure	
8.3	Utilities: HVAC, IQ, OQ	BMS Structure	
8.4	Utilities: compressed air, IQ, OQ	BMS Structure	
8.5	Utilities: chemical storage, IQ	BMS Structure	