Design Transfer Completeness	
Project/Product	*Document number, version, date*

Activity	Responsible	Completed Yes / No		Notes
Design				
Are Design specifications approved (product specifications, material specifications)?				
Was design verification completed successfully?				
Are of all open and/or conflicting points from previous design reviews resolved?				
Is the DHF up-to-date and maintained?				
Risk Management				
Is Product Risk Analysis approved?				
Is Process Risk Analysis approved?				
Have all risk control measures been implement effectively?				
Has there been new or additional information about harms, hazards or failures and was this information added to risk analyses?				
Does product labelling fit risk analysis?				
Manufacturing				
Is the Device Master Record (DMR) approved?				
Is the manufacturing flow chart approved?				
Is the list of materials compiled and up-to-date?				
Was equipment qualification completed successfully?				
Was process validation completed successfully?				
Have all test methods been trained and, if required, qualified/validated?				
Was validation of computerized system completed successfully?				
Is a templates for Lot History Records available?				
Are Production Control plans approved and implemented?				

Activity	Responsible	Completed Yes / No		Notes
Are procedures and controls for microbiological monitoring in place and have limits been established?				
Personnel Training				
Have all operators been trained?				
Are other qualification activities and/or certifications needed and have they been completed (e.g. product training)				
Suppliers				
Have all supplier been qualified?				
Are adequate quality agreements signed by suppliers?				
Are all suppliers listed on the approved supplier list?				
Have major subcontractors been added and have they been approved by notified body?				
Material Control				
Was Product Labeling approved and is manufacturing ready to label?				
Have all materials been added to ERP system?				
Are control plans for incoming inspections in place?				
Are all supporting materials (lubricants, cleaning agents …) approved and labelled?				
Was all remaining development stock removed from manufacturing?				

Approval	
	name / date / signature
	name / date / signature