QA CONSULTING

Project Name:
Date:

The following items are required to be completed prior to product distribution:

Checklist Question	Checklist Response	Evidence/Comments
Is design verification testing complete and acceptable?		
Is design validation complete and acceptable?		
Is the design risk analysis complete and up to date?		
Has usability been reviewed/ tested?		
Is the Device Master Record (DMR) / Medical Device File (MDF) complete?		
Is the Device Identifier Record (DIR) complete and information been submitted to the GUDID?		
Has Unique Device Identification (UDI) information been included in the labeling and directly marked on the product, as required?		

Are supplier evaluations and approvals complete and added to Approved Supplier List (ASL)?		
Are the test method validations complete and acceptable?		
Have personnel been trained?		
Have regulatory approvals been received?		
Has the Approved Product Distribution List been completed?		
Has an ECN been generated to release the specifications (i.e. drawings, labeling) to production?		

Additionally, the following items are required to be complete Design Transfer (Phase V):

Checklist Question	Checklist Response	Evidence/Comments
Is the process risk analysis complete and up to date?		
Have equipment calibration and maintenance requirements been determined?		

Are equipment qualifications and process validations complete and acceptable?		
Is the CE Technical Documentation complete?		

Complete the following if distributing product prior to the completion of Design Transfer (Phase V):

(Instructions are provided in grey text. Delete instructions prior to completion.)

Product	Distribution Location	Rationale/Risk Mitigation
Enter the name and model of the product to be distributed prior to the completion of Phase V	Enter the intended distribution location	Describe the rationale for distributing product prior to the completion of Phase V and any risk mitigation methods to be implemented (e.g. additional inspections, etc.)

Role	Name	Signature/Date
Engineering		
Operations		
QA/RA		