

DESIGN AND DEVELOPMENT PLAN

6.6 Deliverables for each Phase

A table may be used as desired (example see under 6.6.1)

6.6.1 Design Input Phase (according to definition in chapter 5 and corresponding SOP)

Table 3: Design Input Phase example

DELIVERABLE	DESCRIPTION	RESPONSIBLE PARTY
User Requirements Spec.		
Preliminary Hazard Analysis		
Product Requirements Spec.		
And others if applicable		

6.6.2 Design Output (according to definition in chapter 5 and corresponding SOP)

6.6.3 Design Verification (according to definition in chapter 5 and corresponding SOP)

6.6.4 Design Validation (according to definition in chapter 5 and corresponding SOP)

6.6.5 Design Transfer (according to definition in chapter 5 and corresponding SOP)

6.7 Manufacturing

6.7.1 Projected Manufacturing Volume with timeline

6.7.1.1 Device

6.7.1.2 Disposables

6.7.2 Service

6.8 Project Administration

This section describes the activities associated with control of the program. Planned meetings and reviews are listed. Who controls and maintains the DHF is stated.

6.8.1 Meeting Frequency

6.8.1.1 Management meetings

Document Type	Document ID	Version	Status	Page
SOP	XX_WWW_ZZZ_YYYY	1.0	Approved	10/11