I 3 CONSULTING

ISO 13485 Initial Implementation Chart (ONSITE)

Sl.No	Activity	Responsibility	Week-1	Week-2	Week-3	Week -4	Week-5	Week-6	Week-7	Week-8	Week -9	Week-10	Week-11	Week-12	Week-13	Week-14	Week-15	Week-16
1	**Introduction & Understanding the business process**	CONSULTANT (CON)																
2	**Regulatory Compliances**	CON																
3	**Identify duties and responsibilities of all**	CON + HR																
4	**Development of Procedures**	CON + HOD																
5	**Development of SOP,s /Records based on above**	CON + HOD																
6	**ISO awareness training to all staff/employees**	CON + ALL																
7	**Risk analysis**	CON + HOD																
8	**Development of DHR**	CON + HOD																
9	**Product testing (If CE Marking any products)**	CON + MR																
10	**Design & Development activities**	CON + HOD																
11	**Purchase activities**	CON + HOD																
12	**HR activities**	CON + HOD																
13	**Maintenance activities**	CON + HOD																
14	**Development of Quality Policy and objectives**	CON + MR+HOD																
15	**Quality policy/Objective achievement planning**	CON + MR+MD																
16	**Preparation of Quality Manual**	CON + MR																
17	**Preparation of system related procedures**	CON + TEAM																
18	**Understanding the QM/QP/format**	CON + TEAM																
19	**Internal quality Audit Training**	CON + TEAM																
20	**Calibration & Validation**	MR + HOD																
21	**Clinical evaluation records**	CON + TEAM																
22	**Vigilance control**	CON + TEAM																
23	**Preparation of TF (Only in case of CE Marking)**	CON + TEAM																
24	**Verification of Documents and Records**	CON + MR																
25	**Verification of OEM /EU Agreement**	CON																
26	**Verification of Test Reports and data sheets**	CON																
27	**Mock Audit/ Internal Audit**	CON + TEAM																
28	**Closing of Non conformities**	CON + TEAM																
29	**1st MRM**	MR+ MRM																
30	**Stage 1 audit by Notified Body**	NB + TEAM																
31	**Closing of NC,s Observation if any**	CON + TEAM																
32	**Preparatory works for Certification audit**	CON + TEAM																
33	**Certification Audit By Notified Body**	NB + TEAM																
34	**Closing of NC,s Observation if any**	CON + TEAM																