Annex 1

Gemar Regulatory Affairs Services &MORE

GEMAR provides the following services to Medical Devices, Cosmetics, Nutritionals and Pharmaceutical industries:

1. **Research & Development of Medical Devices, Cosmetics, Nutritionals and Pharmaceutical products**

1.1 Projects Management of of Medical Devices, Cosmetics, Nutritionals and Pharmaceutical products, from the idea to the compilation of the Design History File and related tests results,

1.2 Risks Management, Prototyping and Bench Testing, Verification & Validation, Design Transfer,

1.3 Project Management fulfilling products applicable Regulations, Design Control and DHF filing, including definition of Regulatory Affairs data from Design.

2. **Regulaty Affairs International**

2.1 Global Regulaty Affairs consultancies for Medical Devices, Cosmetics, Nutritionals according to applicable laws (e.g. FDA 21 CFR part 820, IVDD 98/79/EC MDD 93/42,and further amendments, MHLW Ministerial Ordinance No. 169, MHLW Ministerial Ordinance No. 2, MHLW Ministerial Ordinance No. 136, Japan PAL, CFDA regulations), including writing of Regulatory Dossiers, preclinical data, Clinical investigation and Clinical Evaluation, Clinical Consulting, Risk Management Files, filing of Regulatory Dossiers, submission to the Authorities and responses to agency queries,

2.2 Global Medical Device Registration and Approval, for Medical Devices, Cosmetics, Nutritionals Manufacturers,

2.3 Service of EC Representative service (AR) and US agent, for Medical Devices, Cosmetics, Nutritionals Manufacturers,

2.4 Global Regulaty Affairs assistance during the product lifecycle for Medical Devices, Cosmetics, Nutritionals Manufacturers.

3. **Quality and Risk Management**

3.1 Consultancy on Quality Management System, according to applicable regulations (e.g. 21 CFR, GMP, ISO 13485, ISO 9001, CMDCAS, Brazilian GMP),

3.2 Internal audits and Suppliers Audits on Quality System requirements, according to applicable regulations (e.g. 21 CFR, GMP, ISO 13485, ISO 9001, CMDCAS, Brazilian GMP),

3.3 Development of Quality Management System, according to applicable regulations (e.g. 21 CFR, GMP, ISO 13485, ISO 9001, CMDCAS),

3.4 GMP, ISO 13485, ISO 9001, CMDCAS and US FDA QSR Consulting and continuous assistance for Medical Devices, Cosmetics, Nutritionals Manufacturers,

3.5 Implementation of Pre-production Quality Management System,

3.6 CMDCAS for medical devices registration in Canada,

4. Process and SW validation

4.1 Process validation according to applicable regulations (e.g. cGMP, FDA Guidelines, GHTF Guidelines)

4.2 Process Validation approaches for:

4.2.1 Small and large molecule Active Pharmaceutical Ingredient (API) manufacture

4.2.2 Pharmaceutical products manufacture (fill/finish type activities),

4.2.3 Cosmetics, Nutritionals and Pharmaceutical products manufacture,

4.2.4 Medical Devices and IVD Devices, Cosmetics, Nutritionals and Pharmaceutical products Packaging,

4.2.5 Medical Devices and IVD Devices manufacture

4.3 Maintaining the Validated State for Medical Devices, IVD Devices, Cosmetics, Nutritionals and Pharmaceutical products manufacture:

4.3.1 Continued Process Verification,

4.3.2 Statistical process control.

4.4 Software validation for Medical Devices, IVD Devices, Cosmetics, Nutritionals and Pharmaceutical products manufacture, according to applicable regulations (e.g. cGMP, FDA Guidelines, GHTF Guidelines)

4.4.1 System specifications

4.4.2 Functional specifications

4.4.3 Security

4.4.4 Back-ups

4.4.5 Validation, *Hardware, Software*

5. Total Preventive Maintenance Process

5.1.1 Support on TPM analysis and improvement.

6. Lean Manufacturing

6.1 Assistance in setting Lean processes - according to Japanese 5S –

6.2 Consultancy in setting Lean concepts and tools to reliminate wastes.

7. Energy Management Process

7.1 Establishing a Management System,

7.2 Energy Audit,

7.3 Energy Saving for Energy-Consuming Systems.

8. Import-Export service for medical devices

8.1 Support to identify suppliers and distributors in the European countries

8.2 Definition of importation procedures from Extra European countries

8.3 Definition of Incoming inspections procedures

8.4 Support in Logistic Management System.