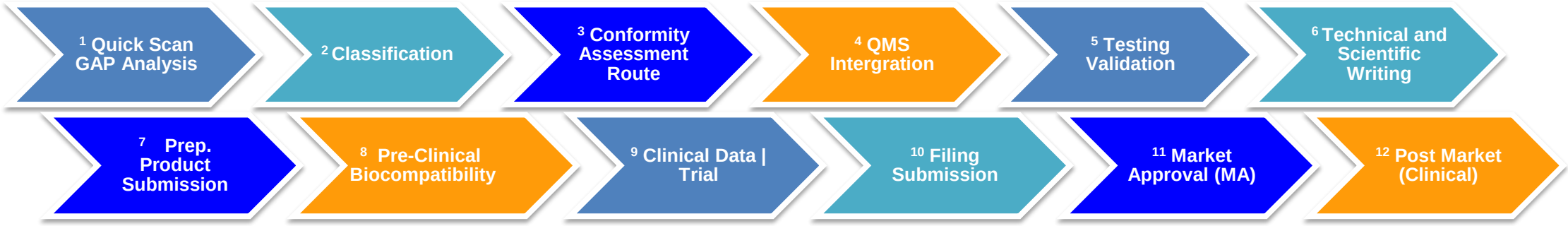
GEMAR
Medical Health Services

Global Project Management Support "One Stop Shopping"



Gemar provides complete **"One Stop Shopping"** support to efficiently secure your Market Approval (MA).
We also provide **training** in all aspects of the development and regulatory process.

1 Quick Scan GAP Analysis

Quick scan or GAP analysis of the Quality Management System or design control upfront of the project will be cost effective by bringing clarity to the status & timing.

2 Classification

Classification assessment/reporting will provide assistance in determining your Conformity Assessment Route for easy market clearance.

3 Conformity Assessment Route

Our experienced lead auditors provide strategic assistance in identifying the optimal conformity assessment route.

4 QMS Intergration

We provide integrated and customized Quality Management Systems suitable for all desired (regulatory) markets

5 Testing Validation

We coordinate & manage your Bench, Electrical Safety, Sterility, Packaging Testing etc. We are experts in Risk Management for Medical Devices

6 Technical and Scientific Writing

Through our own experienced group of Technical Scientific & Regulatory writers, we offer support on all levels.

7 Prep. Product Submission

We compile the Technical and Design Dossiers to latest Regulatory International requirements (STED).

8 Pre-Clinical Biocompatibility

We identify and select Test Houses. We manage and review your Biocompatibility and Pre-clinical Safety Studies.

9 Clinical Data | Trial

Trial planning and development, study start-up, trial monitoring & management, analysis & report, Post Market Clinical Follow-up.

10 Filing Submission

We coordinate action and audits by National Authorities and/ or Notified bodies. We manage the complete submission process up to market entrance.

11 Market Approval (MA)

After obtaining your market approval, we assist you with custom clearance and national entrée globally.

12 Post Market (Clinical)

We coordinate regulatory market (clinical) data analysis with statistical tools. We manage your Vigilance and MDR reporting to Authorities

Europe | The Americas | Asia

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We bring you to market faster!