OPERON STRATEGIST

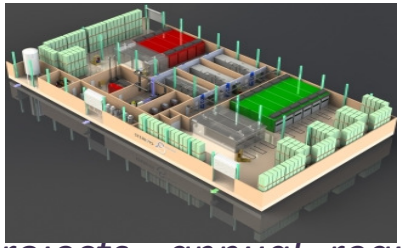
Technical Consulting & Regulatory Advisory Services

Anil Chaudhari (CEO) Email: anil@operonstrategist.com,
Mobile: +91-9823283438

Company Profile

OPERON STRATEGIST is a premier service provider in technical consulting and regulatory advisory. We can assist you for below mentioned services:

- Turnkey Services.
- Quality Assurance.
- Licensing & Certifications.



IQ/OQ/PQ

GMP

ISO Certification

FDA
U.S Food and Drug Administration

We undertake turn key projects, annual regulatory contract as well as functions on the customized packages as per the need of the clients all over the globe.

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Mission

• Our purpose is to serve our clients with unique and matchless Quality and regulatory management services for Medical Devices and Pharmaceutical sector to boost their performance, achieving their targets and meeting their customer, technical & regulatory requirements successfully and being cost effective.

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Our Partners & Alliances

Corporate Office: P-511, Phase I, 5th Level, Mayur Trade Centre, Chinchwad, Pune, 411034, Maharashtra, India.

Alliance with: MDI Consultants, Inc. 55 Northern Blvd., Great Neck, New York 11021, USA.

Partner: Ireland : Tyone, Nenagh, Co. Tipperary, Ireland.

Partner: Room 1912, Building No. 1, Hesheng Qilin She, Chaoyang District, Beijing 100102, P.R.China.

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Organizational Experience

Regulatory Compliance:

Handling/Drafting, Drafting compliances,

CAPA mgmt and Deviations mgmt.

Design and development of Product

Troubleshooting handling for :

QMS

Validations

Process etc.

Turnkey Projects handling right from land selection to regulatory approvals

Microbiological Strategies :

Handling of Analysis, Microbiological tests methods Microbiological aspects of Clean room

510 (k)
CE marking

ISO 9001 / ISO 13485/21 CFR Part 820:

Conceptualization

Documentation

Training Implementation, Handling

Validation:

Equipment

Utilities,

Process,

Analytical methods

Strategy Planning,

Protocol development, Implementation.

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Services Description: *Establisment, Construction & Installation*

Sr. No.	Activity	Description	Client Benefits
1	**Layout Design Preparation**	Technical team collects data and prepares designs as per FDA/Local Regulatory Body norms	Designed as per National or International Regulatory rules and legislations. Detailed Study of FDA laws & regulations
2	**Facility construction**	We assist during the facility build up for selection and positioning of utilities and machineries.	We assist you throughout the project execution time.
3	**DRUG license approved From FDA**	The period required for getting approved Drug license depends on the outcome of FDA audits	Our designed are superior and better than the best. Our rejection/objection rate is nil.
*** We help, for, Verification of facility layout designs feasibility while installation of machinery, Negotiation with Suppliers/ Dealers.**			

Services Description: *Documentation*

Documentation Services:			
Sr.No.	***Services:***	***Benefits***	***Our Speciality***
(i)	**Standard Operating Procedures (SOP)**	• Designed as per the latest National or International Regulatory rules and legislations. Detailed Study of FDA and Local Regulatory Body laws & regulations. • Our Technical team conducts gap analysis, identifies preliminary and final stage requirements and collects the data accordingly.	• Strong Technical competency. Liable for technical responsibilities. • We assist you throughout the project execution time.
(ii)	**Validation Protocols & Validation Reports**		
(iii)	**Site Master File (SMF)**		
(iv)	**Device Master File (DMF)**		
(v)	**Technical File (TF) for CE marking**		

Services Description: *System Implementation*

Sr. No.	Services	Benefits	Insights
1	**System Implementation**	QMS as per : •**ISO** *9001:2008* • **ISO** *13485:2003* • **21 CFR** *-Part 820*	It covers: • Training • System monitoring • Handling **MRM** • Handling **CAPA** • Handling **Deviations** • Internal Audits

Services Description: *Activities, Monitoring & Guidance*

Sr. no.	Parameters	Requirement (for example).	Client Benefits	Our Specialty
a)	**Equipment Utilities & Validation**	Clean Rooms, Sterilizers, Microbial, Microbial, Cleaning, Analytical.	• Best use of available land area to achieve the maximum space utilization • Time to time testing and inspection of machinery always keep an eye on the machinery efficiency and thus save clients huge financial losses • Implementation of best management system practices acts as a tool to achieve larger benefits and makes your system run more effectively and efficiently	• Strong Technical Competency • Time to Time assistance to clients • Thorough knowledge of various National and International standards • Our Charges/Fees is very affordable • Free training to all labours in the company to understand the implementation process of QMS
b)	**Qualification**	Installation Qualification /Operation Qualification/Performanc e Qualification.		
c)	**Certification**	ISO 9001:2008 (QMS), ISO 13485:2003 (Medical Devices), cGMP, CE Marking Consultancy, USFDA, 510 (k)		
d)	**Training**	cGMP, QMS (ISO 9001:2008), training to labours.		

Confidentiality Statement

We obtain and collect data from various organisations which may or may not be confidential in nature.

As a policy of our company, we are bound to maintain all the commercial, data, technical data are kept highly confidential. Sharing confidential information is prohibited or concerned information is made available as per after granting consent from respective authorities.

OPERON STRATEGIST

Quality by design.

Thank You

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