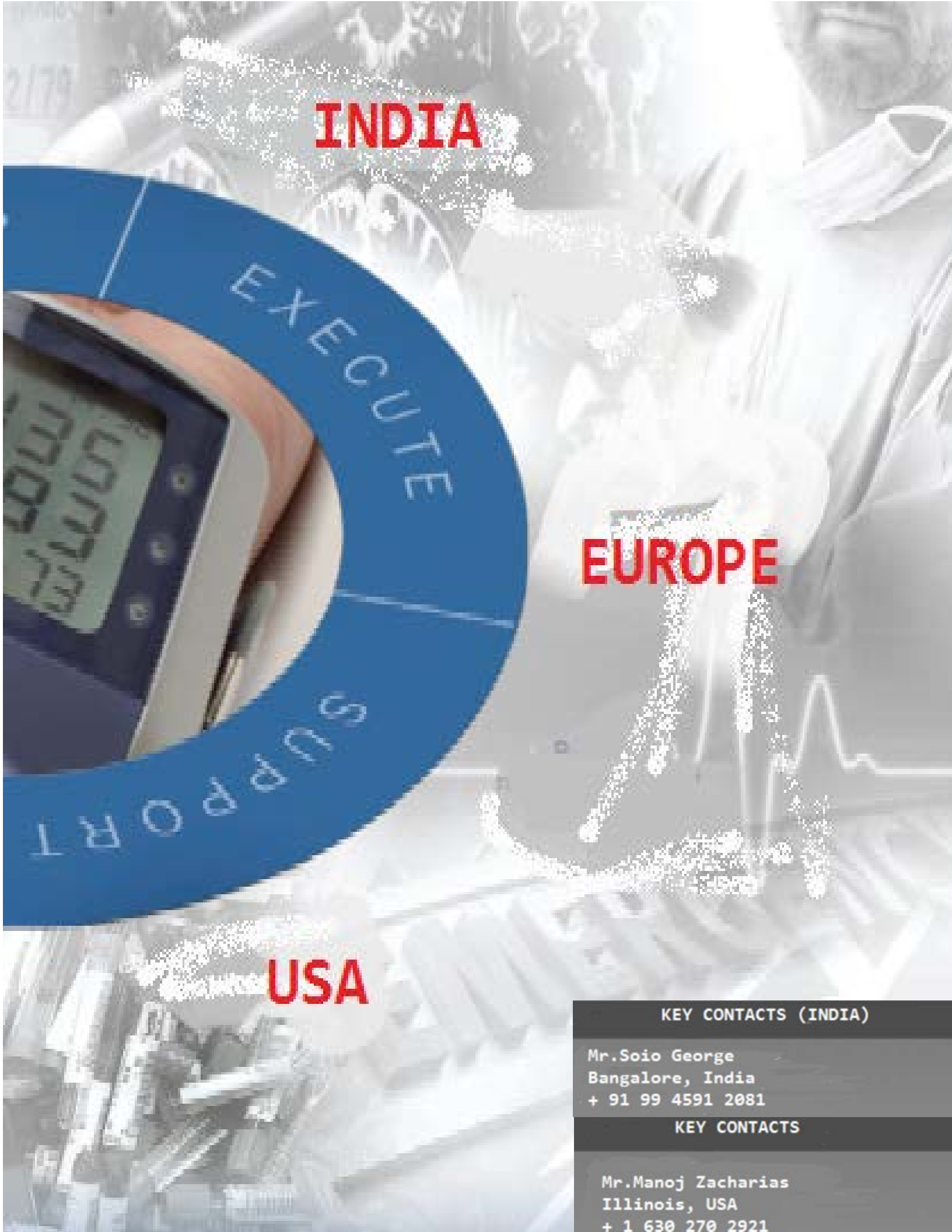
MEDICAL DEVICES

With more than 100,000 individual medical devices on the market, patients have access to an astonishing array of products that can improve health and extend life. But the safety concerns that have accompanied the industry's explosive growth have also produced enormous regulatory pressure and liability exposure.

For more than 10 years, I 3 Consulting have supported medical device manufacturers on every front. We combine our Quality Assurance, Regulatory, Management System and GMP experience to offer cost-effective counsel across multiple disciplines to both early-stage and mature companies. Our focus is on helping clients meet their specific business goals in the areas of:

- Medical Device Manufacturing License
- Facility Layout Design as per various regulatory requirements
- Clean room and HVAC consultation
- Training on International Certifications
- Registration of products in various countries
- Risk Analysis
- ISO 13485 Implementation
- CE Marking
- US FDA
- CMDCAS



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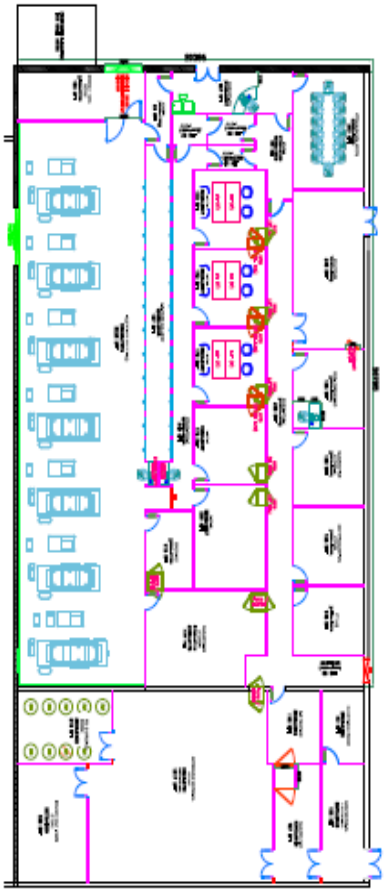
GMP (Good manufacturing practice)

GMP (Good manufacturing practice) is guidance that outlines the aspects of Facility, Process Controls and Quality Inspections that can impact the quality of a product. Pharmaceutics, Medical Device, Food and Cosmetics must follow GMP procedures, and have created their own GMP guidelines that correspond with their legislation.

Therefore, complying with GMP is a mandatory aspect in for proving quality and improving business

Having GMP matters because every individual who wants to buy a Medicine or Device or Dietary supplement would like to be perfectly sure that the product is safe, all the information given on the box is true and that it is not contaminated. It is meant to help not to harm. Especially in case of food and medicine production, meeting the standards of GMP is very important.



GMP Facility Design

A GMP Facility layout

A logical and well-planned layout will improve productivity and avoids unnecessary traffic in the production area which could result in a hazardous environment and also segregate materials, products, and their components to minimise confusion and potential for mix-ups and errors.

B GMP Environment

It's important to control the air, water, lighting, ventilation, temperature, and humidity within a plant so that it does not impact product quality. You should design facilities to reduce the risk of contamination from the environment.

A logical and well-planned layout, proper environmental controls and clean rooms will assure you achieving Certificates like USFDA, CE Marking, CLLA, and ISO 13485

GMP Training

To meet GMP requirements it's essential to have the right people to do the right job. Your employee's have the skills and knowledge to complete their job, so organization needs to equip them with the right tools. If so, then you can be proud that your people are doing the right thing to make GMP a culture

Trainings should provide for all process owners in, whose activities could affect the quality of the product. This includes basic training on the theory and practice of GMP as well as specific training relative to their role.

GMP Documentation

GMP is a collection of documents describing procedures connected with manufacturing and related activities or processes involved. Everybody knows that documentation is critical in GMP, but not anybody can assure of a good structured system of documentation to until a experienced person on job or an experienced consulting group.

GMP facility is regularly audited by the government GMP auditors on a periodic basis. They spend more time on scrutinizing documents, schedules, SOPs, work instructions, records, log books, test data, calibration certificates, and any form of document that will help them evaluate and access the level of compliance.

We used to joke that GMP "Generate more Papers, more employees and more expenses", and this seems true in reality. We have tons of documents to handle. However, there should be no excuse if you are not able to retrieve the particular records required by auditors during their audit, and same will lead to Non compliance.

Bit of advice, do not ignore and take your current document and Facility for granted. Do consult with us before designing for a world class facility

GMP 10 Commandments

1. Get the facility design by GMP expert's right from the start
2. Critical process Validation
3. Write procedures and follow them
4. Define responsibilities of Individuals
5. Online documentation
6. Training
7. Practice good hygiene
8. Maintain facilities and equipment
9. Ensure stability and quality throughout lifecycle
10. Conduct regular internal audits