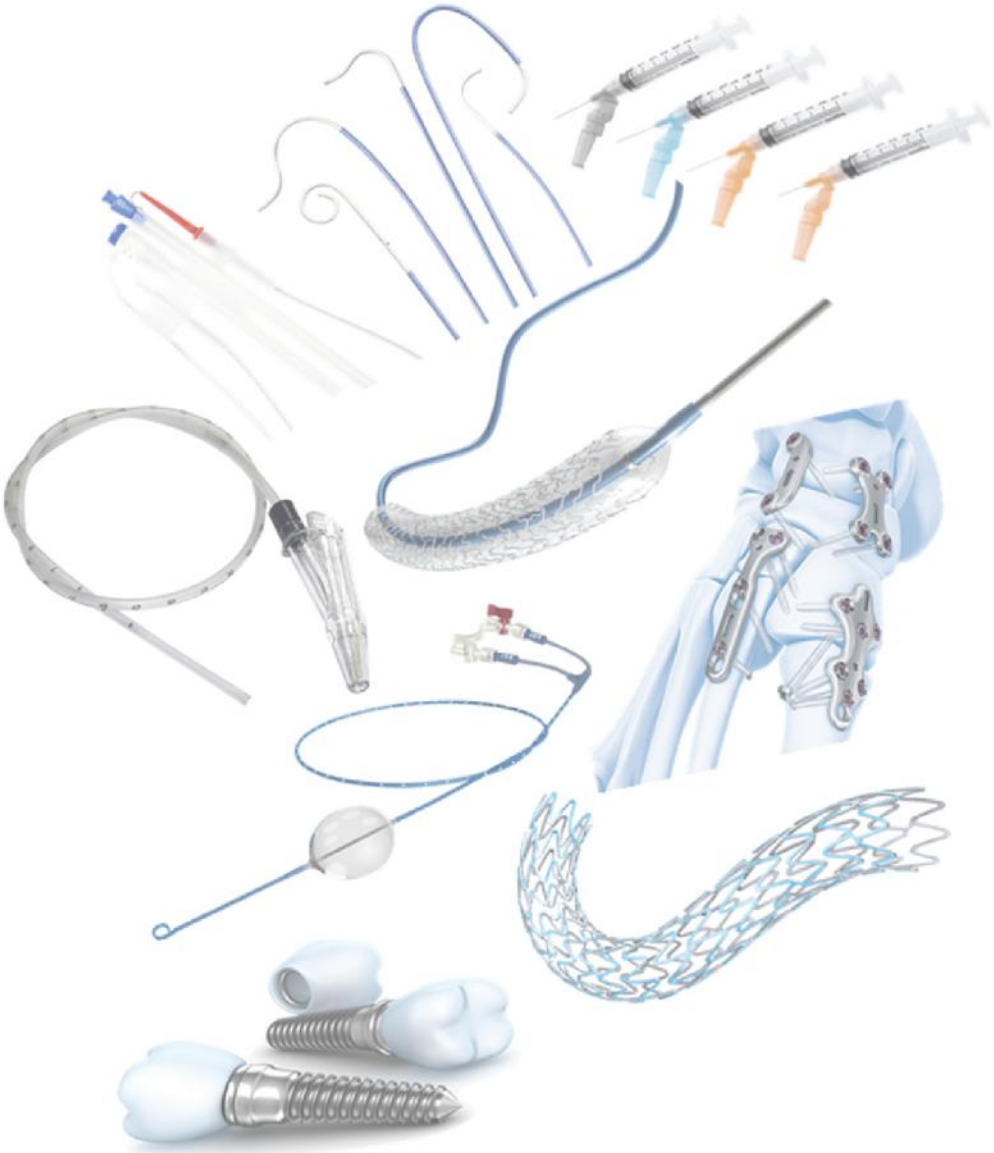
NABL ISO-17025 Accreditated

Liveon Biolabs

Connecting Science To Life

Medical Device Testing CRO



CPCSEA
COMMITTEE FOR THE PURPOSE OF CONTROL AND SUPERVISION OF EXPERIMENTS ON ANIMALS

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, MINISTRY OF HEALTH, GOVERNMENT OF INDIA
CDSCO CDSCO

aaalac INTERNATIONAL

NABL Accredidated Laboratory T-4318

DEPARTMENT OF SCIENTIFIC & INDUSTRIAL RESEARCH, GOVT. OF INDIA
DSIR RECOGNIZED
RECOGNITION FOR IN-HOUSE R&D

ISO 9001:2015

UKAS MANAGEMENT SYSTEMS

www.liveonbiolabs.com

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Biocompatibility testing or 'Biological Evaluation of Medical Devices' (as set out in ISO standard series 10993) is a set of guidelines & testing parameters for assessment of medical device safety before any medical device comes to market. We conduct medical device testing under GLP compliance, which will help the clients for seeking regulatory approval of a product such as CE marking and submission in any regulated international market, for instance European Union or United States.

We have experience with testing of wide range of device types, along with the different methods used to test them. Methods will vary depending on factors such as level of patient contact in terms of duration, and where in the body they are likely to be used or applied. We consider ISO 10993 implications at medical device design, and asses the device functionality and toxicity to the body.

Genotoxicity
Ames Test (Bacterial Reverse Mutation Test)
In vitro and *In vivo* Micronucleus Assay
Chromosomal Aberration Test – CHO cells and Human Lymphocytes
Mouse Lymphoma

Sensitization
Maximization Test (Magnusson & Kligman)
Closed Patch Test (Buehler)
Local Lymph Node Assay (LLNA)

Implantation
Intramuscular, Subcutaneous Implantation
Bone Implantation
Customized Efficacy Studies
Efficacy Studies with Systemic Toxicology

Cytotoxicity
Agar Diffusion
MEM Elution
MTT Cytotoxicity – Quantitative
Neutral Red Uptake (NRU) Cytotoxicity

Toxicity
Acute Systemic Toxicity
Systemic Toxicity (Subacute, Sub chronic & Chronic)
Reproductive & Developmental Toxicity
Carcinogenicity
Pyrogenicity

Irritation
Dermal Irritation
Intracutaneous Irritation
Ocular Irritation
Oral Mucosa Irritation Test
Penile Irritation Test
Rectal Irritation Test
Vaginal Irritation Test

Hemocompatibility
Hemolysis – Direct and Indirect
In vitro Hemocompatibility Assay - Direct and Indirect
Complement Activation – C3a and SC5b-9
Prothrombin Time Assay (PT) – Direct and Indirect
Activated Partial Thromboplastin Time Assay (APTT)

Our scientific team has experience and expertize to evaluate biocompatibility of your new medical device, assess effects of sterilization techniques, impact of any design or process change on your device safety, report writing and answering any queries from international regulatory authorities.

Clinical Services

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Liveon Biolabs offers clinical trial services for your medical device as well as data management and Bio-statistics. We are your partner for an impeccable journey through all clinical trial phases. We will help you in obtaining predictable outcomes, on time, and on budget.

We are well versed with CE-marking requirements and FDA regulations and can assure that your study can be designed and controlled to meet the demands of regulatory bodies, in both the pre-market and the post-market phase of your product. We can conduct the clinical evaluation for you, or support you in the clinical evaluation process.

We have extensive experience in a diverse number of therapeutic areas. Thorough understanding of the specific area of your therapy or device ensures compliance and facilitates in optimally executing your trial. Our unsurpassed network of Key Opinion Leaders enables finding the right sites at the right time.

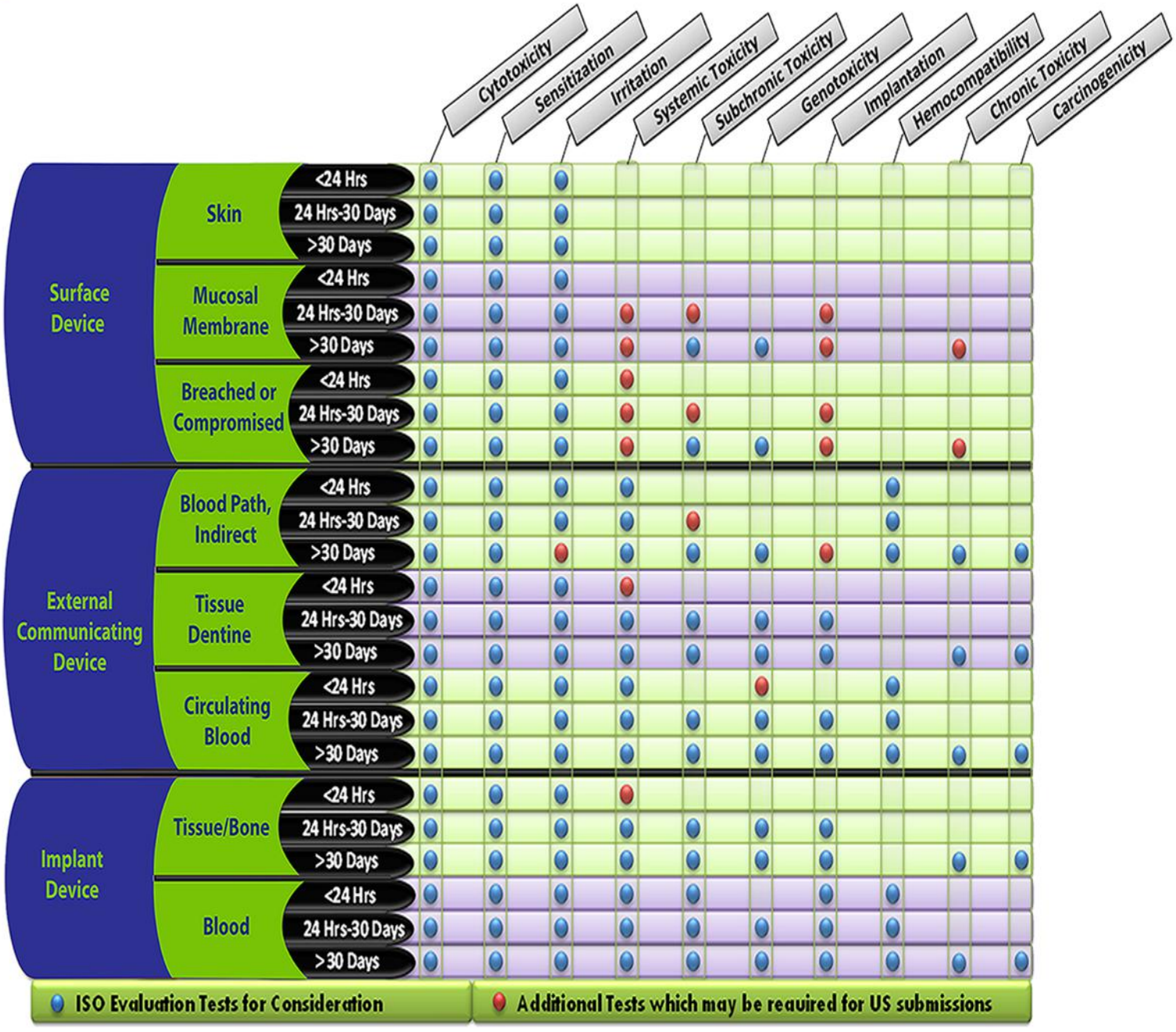
Services

- Clinical and regulatory strategy
- Trial design and validation
- Medical writing
- Clinical monitoring
- Clinical trial management
- Biometrics and data management
- Performance and safety evaluation
- Quality assurance
- Clinical study reports
- Conduct of PMCF studies
- Establishing Post-market registries
- Health economic assessments
- Vigilance reporting

Facility

We conduct in vivo testing in AAALAC-accredited vivarium with 42 animal rooms and dedicated supporting laboratory space, including necropsy rooms, surgical rooms, cage wash areas and various sample preparation and procedure rooms, totalling 24000 sq.ft.

Biocompatibility Testing Matrix



Facility

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