Abich
Analisi biologiche e chimiche
Lifeanalytics

CONSULTING, REGULATORY ASSISTANCE AND EDUCATION

COSMETIC

• **Cosmetic Product Safety Report** according to Regulation (CE) 1223/2009, with signature of a European Registered Toxicologist (ERT).

• **PIF - Product Information File** for cosmetics according to Regulation (CE) 1223/2009.

• **Cosmetic Product Notification** on the web portal CPNP.

• **Formulation design and development** of cosmetic finished products.

• **Development of extraction methods for botanicals.**

• **R&D projects** and support for experimental patents.

• **Assistance for cosmetic labelling ,** according to Regulation (CE) 1223/2009, and environmental labelling.

• **Assistance for new cosmetic plants** and laboratories start-up.

• **Safety Assessment** for ingredients and raw materials.

• **INCI assignment** for new raw materials, MSDS writing.

• **Scientific marketing and communication.**

• **Validation of methods and procedures** for cleaning and sanitization of premises, equipment and plants.

• **Technical education** (toxicology, microbiology, cosmetic testing, regulatory, ISO 22716, design) online and on site (Abich Academy).

• **Customized education** and training on the companies' site.

MEDICAL DEVICES

• **Assistance in the management** of changes from Directive CEE 93/42 (MDD) to Regulation (UE) 2017/ 745(MDR).

• **Support to manufacturers** for the feasability of new medical devices according to MDR.

• **Toxicological and Pharmacokinetic evaluations (ADME)** on bibliographic data with the signature of a European Registered Toxicologist (ERT).

• **Assistance as Person Responsible for the Regulatory Compliance (PRRC)** ex art. 15 MDR.

• **Biological Evaluation Plan** with a chemical and biological testing strategy and Biological Evaluation. Report (BEP and BER) according to ISO 10993-1 .

• **Technical file according to annex II MDR.**

• **Risk assessment** according to ISO 14971.

• **GSPR Table redaction.**

• **Clinical data Evaluation Plan and Report (CEP e CER).**

• **Design and assistance** as a CRO in post-marketing and pre-marketing clinical studies.

• **Assistance in registration** in the EUDAMED data bank for medical devices manufacturers and for products.

• **Assistance in medical devices** labelling according to ISO 15223, ISO 20417 (ex ISO 1041).

• **Support and consulting** for post marketing surveillance (PMS, PMCF e PSUR).

• **Design and R&D for topical products;** manufacturing of pilot batches.

• **Customized regulatory consultancy.**

• **Validation of sterilisation methods.**

• **Technical training and education** (product files, ISO 13485, sterilization, classification, MDR compliance etc) online and on site (Abich Academy).

• **Customized training at the manufacturer's site.**

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MEDICAL-SURGICAL AIDS (PMC) AND BIOCIDES

- **Assistance in the design of safety and efficacy studies.**
- **Technical data sheets and MSDS writing.**
- **Labelling.**
- **Assistance in the notification** to Ministero della Salute and new products filing.

ABICH ACADEMY

Technical and strategical courses for cosmetic, biomedical, textiles and chemical companies.
Webinar and on site training (in Milan, Vimodrone)

- **PIF and CPSR Reg. (CE)1223/2009.**
- **Technical files for MD.**
- **MDR Regulation (UE) 2017/ 745 and MDD Directive CEE 93/42.**
- **Microbiology.**
- **Stability.**
- **In vitro and pre-clinical tests.**
- **Assays on human volunteers.**
- **Clinical investigations for MD.**
- **Good Manufacturing Practices (ISO 22716, ISO 13485).**
- **Risk assessment.**
- **Design of topical products.**
- **Customized training at the client's sites.**

Visit the updated program on:
www.abich.it / Formazione

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