



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 feasibility 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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PRODUCTS.

