



MICROBIOLOGICAL ANALYSIS

BATCH CONTROL

- **Microbiological analysis** on ingredients and finished products (cosmetics, medical devices and similar items): total viable bacteria count, yeasts and moulds count according to methods ISO (21149 e 16212), European Pharmacopoeia / USP, Cosmetics Europe, PCPC; Research of specific microorganisms according to ISO (21150, 22717, 22718, 18416) European Pharmacopoeia / USP, Cosmetics Europe, PCPC.

- **Validation of microbiological analytical methods** on specific matrix according to ISO 11930, European Pharmacopoeia, USP and PCPC.

- **Bioburden on MD** according to UNI EN 11737-1 and sterility assays.

- **Bacterial endotoxins search (LAL Test)** according to USP and European Pharmacopoeia.

- **Isolation and identification of contaminant strains** in products or in the manufacturing premises through DNA / RNA sequencing or o MALDI-TOF or morphological analysis (moulds).

- **Test on surgical masks** UNI EN 14683:2019 annex D Bioburden; UNI EN 14683:2019 annex B; bacterial filtration efficacy (BFE) according to ISO 14683.

PRODUCTS DESIGN (Cosmetics, Medical, Devices, Disinfectants, Biocides, Textiles, etc.)

- **Challenge test** (Test for the efficacy of preservative system) according to methods ISO 11930, European Pharmacopoeia, USP, FDA, Cosmetics Europe, PCPC.

- **Isolation and identification** of contaminant strains of products or manufacturing premises to add them in customized challenge tests.

- **Evaluation of D value** for the determination of PAO (Period After Opening).

- **In-use test in vitro** or on volunteers to evaluate the microbiological stability and PAO

- **Risk assesment for microbial contamination** of cosmetic products according to ISO 29621.

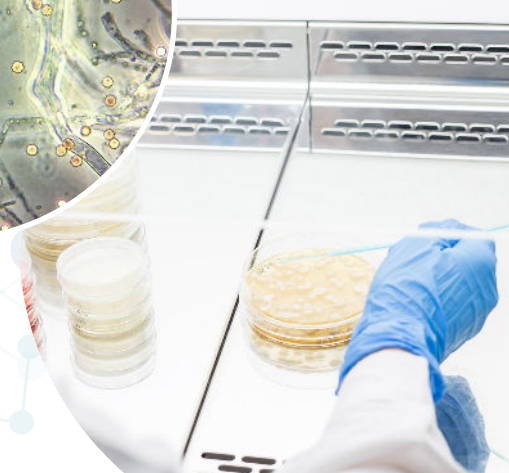
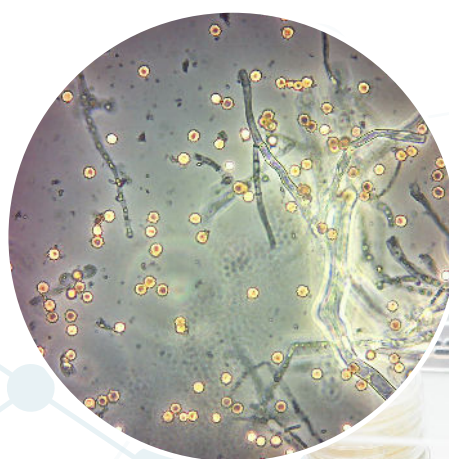
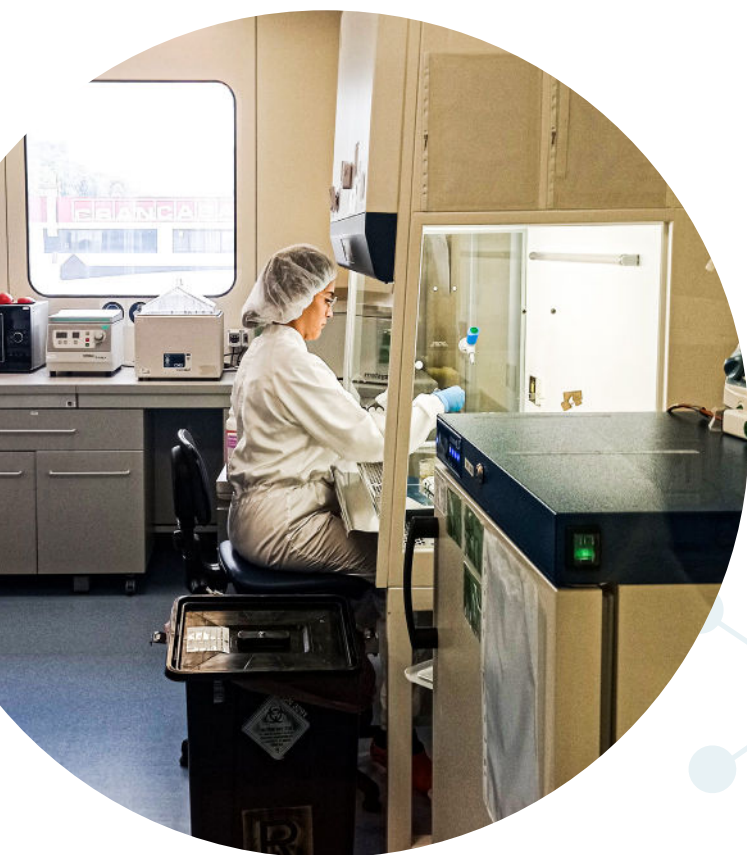
- **Evaluation of the antimicrobial efficacy** of chemical disinfectants and antiseptics according to UNI EN 14885 in medical, domestic, istitutional and veterinary field.

- **Evaluation of specific antimicrobial efficacy** of products or ingredients towards strains of bacteria, fungi, viruses of dermatological or cosmetic interest (MIC, MBC, contact inhibition).

- **Antibacterial activity test** of textiles according to ISO 20645, ISO 20743 and ISO 22196

- **Test for the evaluation** of the action of microfungi on textile products according to UNI EN 1411.

- **Virucidal activity of chemical disinfectants**, antiseptics and similar products according to UNI EN 14476, UNI ISO 16777, ISO 21702, ISO 18184 (more additional virus strains, like coronavirus, are also available).





MICROBIOLOGICAL ANALYSIS

• **Evaluation of the efficacy of finish products** or active ingredients on the skin microbiome modification through in vitro preliminary assays and test on selected panel of human volunteers.

• **Search for bacterial endotoxins (LAL Test)** according to USP and UE Pharmacopoeia.

• **Evaluation of the efficacy of environmental disinfection** by aerodisperse methods according to UNI EN 17272:2020.

• **Evaluation of the modification of bacterial adhesion** towards mammal cells by medical devices, supplements or active ingredients.

• **Mutagenesis assay (test di Ames)** according to OECD 471.

• **Design of customized testing protocols** and method validations on the bases of the sponsor's needs.

CONTROL OF MANUFACTURING PREMISES

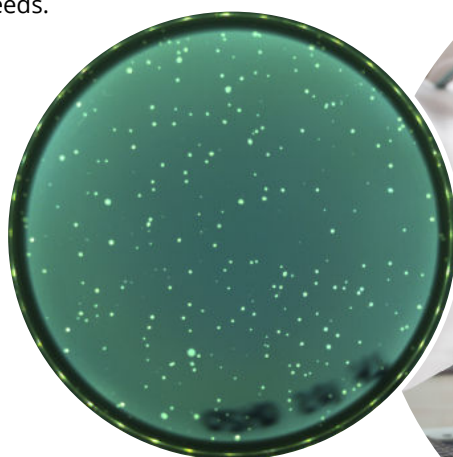
• Environmental analysis of aerodisperse microorganisms by air sampling with SAS SUPER IAQ "Surface Air System".

• Environmental analysis of the microbial contamination of surfaces in manufacturing plant, equipments and laboratories.

• Validation of cleaning and sanitisation procedures and protocols for manufacturing plant and premises in cosmetic and biomedical facilities.

• Design of testing protocols and customized validations on specific needs of the client.

Quality systems and certifications: GLP (Italian Ministero Salute), ISO 17025, ISO 13485, ISO 9001, GMP (Montreal site).



CONTACT

Italy Abich Srl

Registered Office and Laboratory Analysis
Via Quarantadue martiri 213/b
28924 Verbania (VB) - **Italia**
Tel. +39 0323 586239 / 496041

Clinical and Cosmetic Studies
Via L. Cadorna, 67 - Edificio A/1
20055 Vimodrone - Milano - **Italia**

www.abich.it

USA / Canada Abich Inc.

Registered Office and Laboratory Analysis
5160 Decarie Blvd #330,
Montreal, Quebec H3X 2H9,
Canada
Tel. +1 514 507 9982

www.abich.ca

sales@abich.it
info@abich.ca

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CHEMICAL-PHYSICAL ANALYSIS FOR QUALITY CONTROL

• **Instrumental analysis** by HPLC and UHPLC with UV/ DAD/RID detector.

• **Instrumental analysis** by GC-FID, GC-MS, ICP-OES, FT-IR/ UATR, UV-VIS.

• **Quantification** of active ingredients and preservatives in cosmetics and medical devices.

• **Analysis** of multiresidual impurities and of trace contaminants in finished products and ingredients, like for example: phthalates, nitrosamines, VOC, substances listed in annex II of regulation (CE) 1223/2009.

• **Chemical characterization of medical devices** according to ISO 10993-18: extractables and leachables

• **“Paraben free”**: ultra-traces analysis to support the claim “Paraben-Free” in finished cosmetic products, control of preservatives residue on manufacturing plants and « cleaning validation”.

• **Allergenes**: analysis of allergenes in cosmetic finished products and ingredients from natural sources.

• **“Nickel Tested”**: control on product batches and intermediates bulks to support the claim “Nickel Tested”.

• **Metals**: analysis of inorganic contaminants in finished products and raw materials; toxic metals like Hg, Cd, As, Pb and sensitising metals like Ni, Cd, Co, Cr. Cosmetic relevant metals: As, Sb, Cd, Hg, Ni, Co, Cr, Pb e Cr VI.

• **Metals**: ICH guideline Q3D (R2) on elemental impurities - Table 5.1: elements to be considered in the risk assessment – oral, parenteral and inhalation exposure.

• **Release test in artificial sweat or saliva** for the detection of sensitising metals in cosmetic anhydrous

and solid products; Release test in artificial sweat or saliva according to ISO 10993-12 for substances or impurities in medical devices.

• **Validation of analytical methods** according to ICH Guidelines for medical devices and for products to be marketed on the USA and European market.

• **Test and analysis to support specific claims**, customized according to the sponsor's needs.

• **Test and analysis** to support “cleaning validation” processes.

• **Percutaneous and permucosal** absorption test through Franz cells (OECD 428 and FDA methods): many epithelial and epidermis human models as well as synthetic membranes.

• **Stability assays** according to ICH for medical devices, to CIPAC for PMC e Biocides, to ASTM or PCPC for cosmetics. Chemical-physical and microbiological analysis.

• **Packaging compatibility.**

• **Photostability of sun products** with SUN TEST – sunscreens analysis and evaluation of decay before and after Uv exposure.

• **E-cigarettes and aromes**: safety and toxicity analysis.

• **Botanical extracts analysis.**

• **Control of manufacturing** for batches of PMC and Biocides.

• **Quality control**: analysis of osmolality, surface tension, viscosity, density, drop point, softening point etc. on ingredients, bulks and manufacturing product batches.





CHEMICAL-PHYSICAL ANALYSIS AND ASSAYS TO SUPPORT PRODUCT DEVELOPMENT

• **Stability assays** according to ICH for medical devices, to CIPAC for PMC e Biocides, to ASTM or PCPC for cosmetics. Chemical-physical and microbiological analysis.

• **Compatibility with packaging**, analysis of impurities and contaminants released or absorbed by the packaging components.

• **Photostability of sun products** with SUN TEST – sunscreens analysis and evaluation of decay before and after UV exposure.

• **Chemical characterization of medical devices** and components of for BEP/BER (Biological Evaluation Plan and Report).

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• **Percutaneous and permucosal absorption test through Franz cells** (OECD 428 and FDA methods): many epithelial and epidermal human models available as well as synthetic membranes to select according to the product destination and use. Identification and development of the analytical method.

• **E-cigarettes and aromes**: safety evaluation and toxicological analysis for components and ingredients with in-use simulation.

• **Characterisation of botanical extracts** and development of the extraction method for the industrial scale-up.

• **Mucoadhesion assay**: adhesiveness test to verify and compare the physical adhesion properties of medical devices and products aimed to be used on mucosae.

• **Compatibility** with condoms according to ASTM D6771 or ISO 19671 standards through traction and explosion tests.

• **In vitro UVA pf and broad spectrum UV** protection according to ISO 24443: and to Boots Star Rating; in vitro water resistance and variants.

• **In vitro blue light protection** and far UVA protection evaluations.

• **Trichological tests in vitro on human hair** locks to support customized cosmetic claims Test like for example: resistance to break, combability, color strenght and many others.

• **Customized tests on hair treatments** according to the sponsor's needs.

• **UV protection test for Medical adhesive** and Textiles according to EN 13758.

Certificazioni e sistemi di qualità:
BPL (Ministero Salute),
ISO 17025, ISO 13485,
ISO 9001.



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IN VITRO TEST

SAFETY AND TOXICOLOGICAL ASSAYS

- **Cytotoxicity assays on cosmetics**, ingredients and medical devices according to UNI EN ISO 10993-5.
- **Predictive assays for skin irritation** on cell monolayers (fibroblasts, keratinocytes).
- **Irritation test** on 3D reconstituted human epidermis (OECD439).
- **Skin irritation test** on 3D reconstituted human epidermis for medical devices (ISO 10993-23).
- **Irritation tests** on 3D reconstituted human epithelia (vaginal, gingival, oral, respiratory...).
- **Skin corrosion tests** (OECD 431, 435).
- **Eye irritation tests** (OECD 491, 492, 492B, 496).
- **Eye corrosion test** (OECD 460).
- **Skin sensitisation assay OECD 442D** (keratinosens).
- **Skin sensitisation assay OECD 442E** (IL-8 Luc Assay, hCLAT, GARDTM).
- **Skin sensitisation assay** on 3D reconstituted human skin (IL-18 RHE Assay, SENS-IS).
- **Phototoxicity assay** (OECD 498 on 3D epidermis).
- **Phototoxicity assay** (OECD 432 on cell monolayers).
- **Mutagenesis assay** (Ames) (OECD 471): screening and full test.
- **Ecotoxicity assay on Daphnia Magna** (OECD 202) and algae (OECD 201).
- **Biodegradability test** (OECD 301F).
- **Carcinogenesis in vitro assay** (OECD guidance document n. 231).
- **Mutagenesis assay in mammal cells** (Comet assay).

• **Assays for the evaluation** of hormonal endocrin disruptor effects (OECD 456, 458, 455).

• **Percutaneous absorption test with Franz cells Test** on human reconstituted 3D epidermis and epithelia, on ex vivo epidermis, on wounded epidermis etc.

• **Cytotoxicity assays** to estimate in vitro the oral LD50 value (OECD guidance document 129).

EFFICACY TESTS

• **Antioxidant and anti- free radicals activity** on skin-derived cells (ROS analysis on keratinocytes and fibroblasts) following chemical or physical stress.

• **Direct antioxidant activity assay** (es ORAC TEST).

• **Antiaige activity/derma ridensifying activity:** mitogen effect, stimulation of the proteins synthesis, increase of the synthesis of proteins of the extracellular matrix (collagen, elastin, fibronectin, etc).

• **Barrier effect test** on human 3D reconstituted epithelia and epidermis.

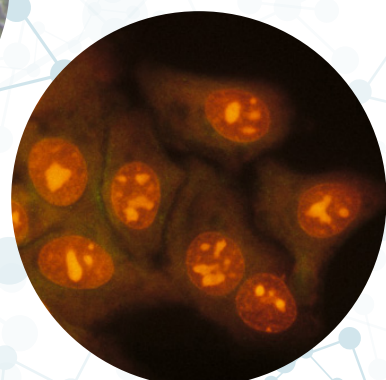
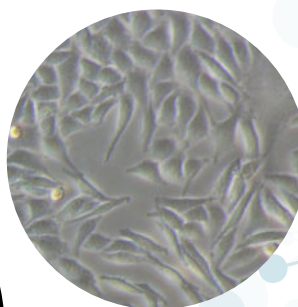
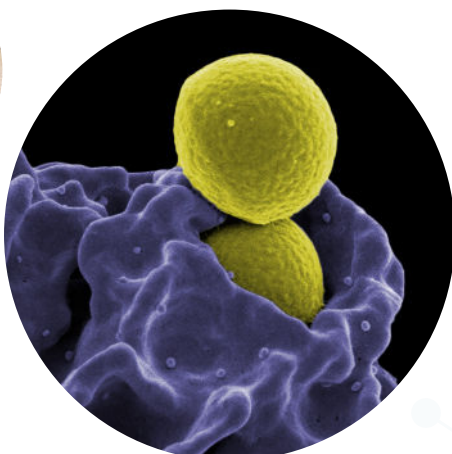
• **Evaluation of the keratolitic effect** with test on human 3D reconstituted epidermis.

• **Wound healing activity assays** on endothelial cells and fibroblasts (healing products and ingredients, anti-stretchmarks products).

• **Test for the evaluation of the effect** on melanogenesis (increase/reduction of the melanine synthesis by whitening or tanning products) both on monolayer cells or on 3D human in vitro pigmented epidermis.

• **Assay for the evaluation of tirosinase gene expression** on monolayer cells.

• **Assay for the direct evaluation of the modulation of enzymatic activity** (i.e. Tirosinase, Acetilcolinesterase, Collagenase and other metalloproteinases).





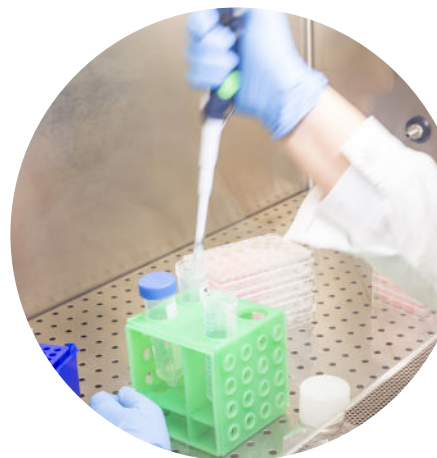
IN VITRO TEST

- **Anti-inflammatory activity assays** on human 3D reconstituted epithelia and epidermis.
- **Test to evaluate the immune response** through analysis of specific mediators (i.e. Histamine, IL-1 α , TNF- α) to evaluate anti-itching activity, inhibition of sensitisation, immunostimulating activity etc.
- **Test for the evaluation** of cell senescence.
- **Test for sebum control activity** (inhibition of lipase).
- **Evaluation of the inhibition of 5- α reductase enzyme** (hair growth, acne, sebum regulation).
- **Skin hydrating activity of cells** in monolayer or 3D reconstituted epidermis.
- **Anti-pollution efficacy** against smog and toxic chemicals.
- **Lipolytic activity on adipocytes.**
- **Inhibition of neo-angiogenesis** through analysis of VEGF expression (i.e. anti-couperose products).
- **Test to support barrier effect** towards heat (IR) on human 3D reconstituted epidermis.
- **Percutaneous absorption tests with Franz cells** on human 3D reconstituted epithelia and epidermis, on ex-vivo epidermis, on wounded epidermis to evaluate the permeation of ingredients, the efficacy of carriers or the barrier effect against permeation.
- **In vitro test of products for acne rosacea treatment** through the analysis of gene expression of markers involved in skin inflammation and linked to rosacea.
- **Customized protocols and R&D projects.**

PHYSICAL PERFORMANCE IN VITRO ASSAYS

- **Mucoadhesion assay:** gravimetric test to verify and compare the physical adhesion properties of medical devices and products aimed to be used on mucosae.
- **Compatibility with condoms** according to ASTM D6771 o ISO 19671 standards through traction and explosion tests.
- **In vitro UVApf and broad spectrum UV protection** according to ISO 24443:2021 and to Boots Star Rating; in vitro water resistance and variants.
- **In vitro blue light protection and far UVA protection evaluations.**
- **Trichological tests in vitro on human hair locks** to support customized cosmetic claims Test like for example: resistance to break, combability, color strenght and many others.
- **Customized tests on hair treatments** according to the sponsor's needs.

Quality systems and certifications:
GLP (Italian Ministero Salute), ISO 13485, ISO 9001.



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COSMETOLOGICAL AND CLINICAL TESTING

SAFETY TESTING

- **Patch test, Repeated Insult Patch test**, Patch test on sensitive skin, for cosmetics and similar products.
- **Evaluation of sensitisation risk** and claim hypoallergenic with HRIPT (Human Repeat Insult Patch Test) on cosmetic products.
- **Dermatological, ophtalmological and gynaecological in-use tests** on volunteers to evaluate the tolerability of cosmetic products.
- **Sun product tests**: SPF and Water Resistant (ISO 24444:2019 Amd 1.2022, ISO 16217/18861:2020 FDA vol 76 n° 117 of 17 June 2011) SPF UVA PPD according to ISO 24442:2022, test for SPF long lasting, test for SPF according to Australian method AS/NZS 2604: 2021.
- **SPF on wet skin, SPF Water/Sand/Sweat resistance, SPF persistence for sun products.**
- **Photo-patch test** for cosmetic products.

• **Sensorial analysis** and administration of questionnaires to selected panels of healthy volunteers.

• **Anti-wrinkles test through quantitative analysis** of profilometry and skin imaging with 3D blue laser scanner (DERMA TOP-Blue) or with 3D imaging (ANTERA).

• **Skin elasticizing, firming/tonifying activity tests** through skin probes.

• **Evaluation of skin barrier performance** (TEWL - Trans Epithelial Water Loss), Arm Wash Test.

• **Test for anti-eye and anti-eye circles activity** through volumetric analysis, skin dermatography and skin colorimetry.

• **Skin depigmentation, belaching and lightening tests** through Chromameter or Antera imaging.

• **Skin darkening and increase of tanning speed test.**

• **Anti-cellulitis activity test** through Antera or Derma TOP-blue.

• **Test for skin sebum reduction** through Sebumeter.

• **Comedogenesis assays.**

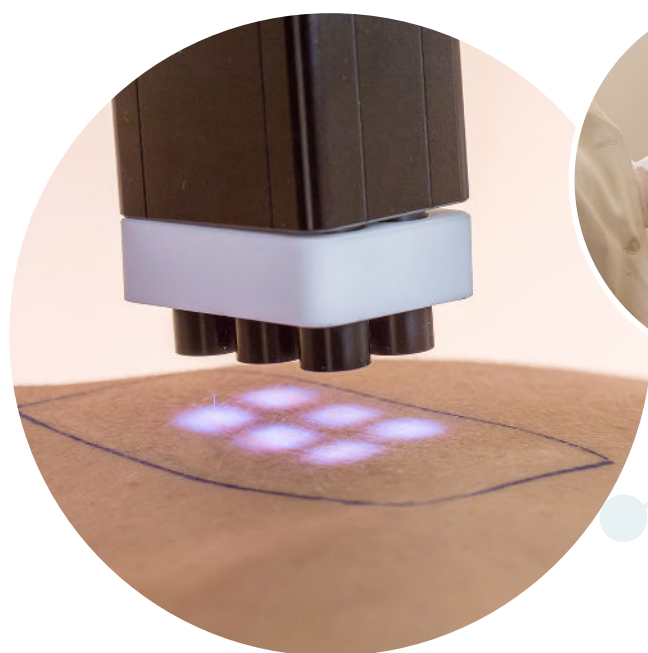
• **Anti perspirant activity test**, 24 h or 48 h lasting (FDA method with sauna) and deodorizing activity (Sniff Test).

• **Skin soothing activity test** with irritation induced by chemicals or with UV-rays

• **Long-lasting test for make-up** for face, lips and eyelash.

EFFICACY AND PERFORMANCE TESTING

- **Tests for short and long-term** skin moisturization through corneometry and/or TEWL measures.
- **In-use test on selected human volunteers panels** for the evaluation of the efficacy of cosmetic products under medical supervision (dermatologist, allergologist, gynaecologist, ophtalmologist, dentist etc.).





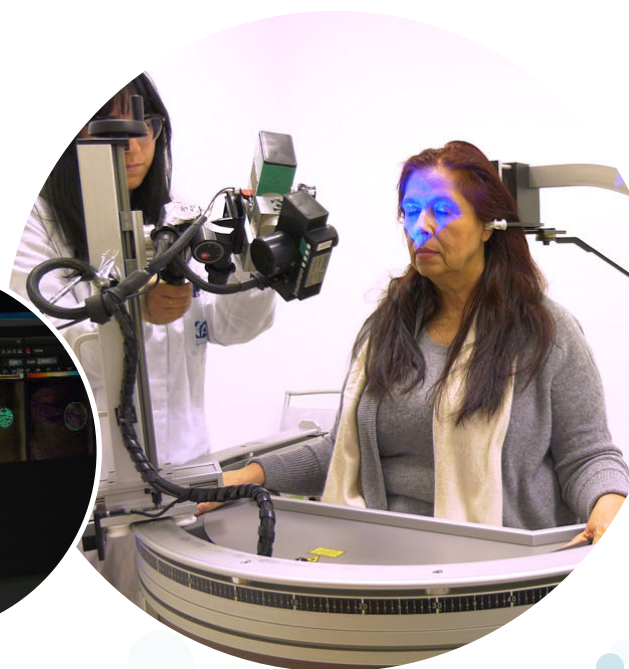
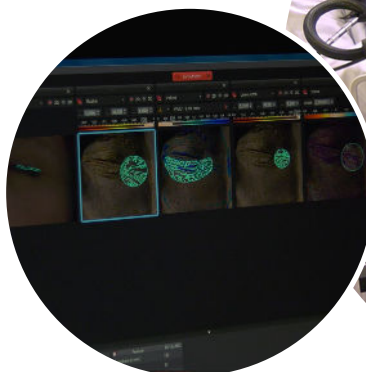
COSMETOLOGICAL AND CLINICAL TESTING

- **Lip-volumizing activity test** for lip and eyelash make-up.
- **Efficacy tests for trichological products:** anti-dandruff activity, hair fall prevention and hair growth activity with TrichoScan, hair viability, color strenghtness etc.
- **Test for Sun products:** SPF, Water Resistant and Very water Resistant (ISO 24444: 2019 Amd 1:2022, ISO 16217/18861:2020, FDA vol 76 n° 117 of 17 June 2011), SPF UVA PPD according to ISO 24442: 2022, SPF long lasting Test, test SPF according to Australian method AS/NZS 2604: 2021.
- **SPF on wet skin, SPF Water/Sand/Sweat resistance, SPF persistence.**
- **Evaluation of the antimicrobial efficacy** of chemical disinfectants and antiseptics according to UNI EN 14885 in medical, domestic, istitutunal and veterinary field
- **Usability tests** for medical devices
- **Efficacy studies for supplements** for healthy skin, mucosae and cutaneous annexes.

OTHER STUDIES

- **Post-marketing clinical studies** on medical devices according to UNI EN ISO 14155.
- **Medical and technical assessments** of ethical clearance also for external studies
- **Assessment by an independent Ethical commette.**
- **Patients recruitment for clinical investigations** of medical devices and IVD.
- **Pediatric expertises** for cosmetic products intended for childrens and babies use.

Quality systems and certifications:
GLP (Italian Ministero Salute),
ISO 13485, ISO 9001,
FDA (Montreal site).



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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.**





CONSULTING, REGULATORY ASSISTANCE AND EDUCATION

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:
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