BIOM ADVICE

Make standards and regulations your strength to conquer new markets

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CONSULTANT, Engineer, Toxicologist

Expertise: Biological evaluations (ISO10993), Toxicological evaluations (TRA), Clinical evaluations (CER), Process validation, Audits, ISO13485, ISO17025, EC marking, Training

PROFESSIONAL EXPERIENCE

2013- BIOM ADVICE

2013- BioM ADVICE – Independent consultant
- Clinical evaluation per MDR, Biological evaluation ISO 10993-1, Toxicological assessment ISO 10993-17, Process validation, Audits, EC marking files, Regulatory technical and QMS advice
- Technical expert in ISO TC194 committee on "Biological and clinical evaluation of MD"
- Technical expert in ISO TC150 committee on "surgical implants" from 2008 to 2017
- ISO17025 and ISO 13485 auditor
- Trainer (Biological evaluation ISO 10993, sterilization ISO 11137, audit ISO 19011…)

2002-2013 MEDICAL GROUP

2010-2013 MEDICAL LAB General Manager
- MEDICAL LAB General Manager (R&D, Microbiology tests, Mechanical and physicochemical tests on MD, Cleaning, packaging and sterility validations), ISO17025
- Participation in AFNOR and ISO TC150 committees

2007- Coating, packaging and biomaterials expert, Technical manager
- Technical manager for Plasma spray coatings on MD, Cleaning and packaging of MD and Manufacturing of biomaterials, ISO13485

2002- R&D engineer, regulatory affairs
- Project manager: Risk analysis, Functional specification, Value analysis…
- VMP, IQ, OQ, PQ process validations: Manufacturing, cleaning, packaging, sterilization.
- Quality management system for manufacturing activities.
- Regulatory files and survey: EC marking, 510(k), Master File (MAF)

EDUCATION

Continuous training

2026	**EFOR -** 21CFR (QMSR) US regulation for medical devices
2024	**MD101 –** Regulatory requirements of MDSAP jurisdictions (US, Canada, Australia, Brazil)
2023	**CPE -** Determination of molecular structure by mass spectrometry
2022	**BSI** - ISO 13485: 2016 clause by clause
2021	**Univ. Paris** - Toxicology Basics: Study of methodological mechanisms and approaches
2020	**BSI** - ISO 14971: 2019 Application of risk management to medical devices
2019	**LNE** - Clinical evaluation of medical devices (MEDDEV 2.7/1 Rev.4)
2018	**CPE** - Toxicology applied to health hazards
2018	**MD101** - 2017/745 regulation on medical devices
2017	**CEFIRA** - Toxicological evaluation of impurities in drug products
2017	**BSI** - Training of the trainer
2016	**LNE** - Internal and supplier audit according to ISO13485 and ISO19011
2015	**MEDIQUAL** - Application of usability engineering to medical devices (EN 62366)
2014	**TUV** - Biocompatibility of product and process (ISO 10993)
2014	**AFNOR** - Rules for drafting standards
2013	**COFRAC** - ISO/CEI 17025 Technical auditor of testing laboratories
2012	**CCI** - Strategy for SME – sales techniques
2010	**Consultant** - Management coaching
2007	**IFIS** - Materiovigilance management
2006	**LNE** - 510(k)

Education

2024	**Univ. Paris Cité** MASTER Toxicology and Ecotoxicology (THERV: Human toxicology, Evaluation of risks and vigilances)
1999-2002	**PhD** « Development of HA/TCP bone substitutes with antibiotic » (collaboration between MEDICAL GROUP and MATEIS lab of INSA Lyon)
1994-1999	**INSA Lyon** engineer school, specialization in materials

LANGUAGES

Languages	French: mother tongue	English: fluent

PUBLICATIONS – PATENTS - STANDARDS

SCIENTIFIC PUBLICATIONS

- BIGNON A., CHEVALIER J., FANTOZZI G. *Effect of ball milling on the processing of bone substitutes with calcium phosphate powders.* Journal of Biomedical Material Reasearch, Applied Biomaterials, 2002, 63, 5 : 619-626.
- CHOUTEAU J., BIGNON A., CHAVASSIEUX P., CHEVALIER J., MELIN M., FANTOZZI G., BOIVIN G., HARTMANN D., CARRET JP. *Culture cellulaire d'ostéoblastes et de fibroblastes sur substitut osseux poreux en phosphate de calcium.* Revue de chirurgie orthopédique, 2003, vol. 89, p. 44-52.
- BIGNON A., CHOUTEAU J., CHEVALIER J., FANTOZZI G., CARRET J-P., CHAVASSIEUX P., BOIVIN G., MELIN M., HARTMANN D. *Effect of micro and macroporosity of bone substitutes on their mechanical properties and cellular response.* Journal of material science : materials in medecine, 2003, vol. 14, p. 1089-1097.
- LAURENT F., BIGNON A., HARTMANN D., GOLDNADEL J., CHEVALIER J., FANTOZZI G., VIGUIER E., ROGER T., BOIVIN G. *A new concept of gentamicin loaded HAP/TCP bone substitute for prophylactic action - in vitro release validation.* Journal of material sciences: materials in medicine, 2008, vol.19, n°2, p. 947-951
- VIGUIER E., BIGNON A., LAURENT F., GOEHRIG D., BOIVIN G., CHEVALIER J. *A new concept of gentamicin loaded HAP/TCP bone substitute for prophylactic action - in vivo pharmacokinetic study*, Mater Sci: Mater Med (2011) 22:879–886

PATENTS

- WO2006013244: METHOD FOR COATING AT LEAST A PART OF A MEDICAL PROSTHESIS SURFACE WITH ONE OR SEVERAL ANTIBACTERIAL AGENTS (2006)
- FR2993183: COMPOSITION OF INJECTABLE BONE SUBSTITUTE (2014)

STANDARDS (Project leader)

- ISO 13175-3 (2012): Implants for surgery - Calcium phosphates - Part 3: Hydroxyapatite and beta-tricalcium phosphate bone substitutes
- ISO 13779-2 (2018): Implants for surgery - Hydroxyapatite - Part 2: Coatings of hydroxyapatite
- ISO 13779-4 (2018): Implants for surgery - Hydroxyapatite - Part 4: Determination of coating adhesion strength
- ISO 13779-6 (2015): Implants for surgery - Hydroxyapatite - Part 6: Powders
- ISO 13179-1 (2014): Implants for surgery - Plasma-sprayed unalloyed titanium coatings on metallic surgical implants - Part 1: General requirements
- ISO 19227 (2018): Implants for surgery - Cleanliness of orthopedic implants - General requirements

STANDARDS (Active participation as an expert)

- ISO 10993-12 (2021): Biological evaluation of medical devices — Part 12: Sample preparation and reference materials
- ISO 10993-17 (2023): Biological evaluation of medical devices — Part 17: Toxicological risk assessment of medical device constituents
- ISO 10993-18 (2020): Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process
- ISO 8250 (new standard under creation): Cleanliness of medical devices – Process design and test methods
- ISO 10993-1 (under revision): Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- ISO 18969 (new project): Clinical evaluation of medical devices
- ISO/TS 20324 (new project): Generation of medical device extracts for chemical analysis to support toxicological risk assessment
- ISO/TS 25364-1 (new project): Analytical Chemistry Matters Associated with ISO 10993-18 - Part 1: Identification of Organic Medical Device Extractables and Leachables in Non-Targeted Analysis (NTA)
- ISO/TS 25364-2 (new project): Analytical chemistry matters associated with ISO 10993-18 - Part 2: Quantification of medical device extractables and leachables using Non-Targeted Analysis (NTA)
- ISO/TS 25364-3 (new project): Analytical Chemistry Matters Associated with ISO 10993-18 - Part 3: Instrumental and Human Requirements for Evaluating Organic Medical Device Extractables and Leachables via Non-Target Analysis (NTA)