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## CONSULTANT, Engineer, Toxicologist

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



### PROFESSIONAL EXPERIENCE

<b>2013- BIOM ADVICE</b>	<p><b>2013- BioM ADVICE – Independent consultant</b></p> <ul style="list-style-type: none"> <li>✚ 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</li> <li>✚ Technical expert in ISO TC194 committee on “Biological and clinical evaluation of MD”</li> <li>✚ Technical expert in ISO TC150 committee on “surgical implants” from 2008 to 2017</li> <li>✚ ISO17025 and ISO 13485 auditor</li> <li>✚ Trainer (Biological evaluation ISO 10993, sterilization ISO 11137, audit ISO 19011...)</li> </ul>
<b>2002-2013 MEDICAL GROUP</b>	<p><b>2010-2013 MEDICAL LAB General Manager</b></p> <ul style="list-style-type: none"> <li>✚ MEDICAL LAB General Manager (R&amp;D, Microbiology tests, Mechanical and physicochemical tests on MD, Cleaning, packaging and sterility validations), ISO17025</li> <li>✚ Participation in AFNOR and ISO TC150 committees</li> </ul> <p><b>2007- Coating, packaging and biomaterials expert, Technical manager</b></p> <ul style="list-style-type: none"> <li>✚ Technical manager for Plasma spray coatings on MD, Cleaning and packaging of MD and Manufacturing of biomaterials, ISO13485</li> </ul> <p><b>2002- R&amp;D engineer, regulatory affairs</b></p> <ul style="list-style-type: none"> <li>✚ Project manager: Risk analysis, Functional specification, Value analysis...</li> <li>✚ VMP, IQ, OQ, PQ process validations: Manufacturing, cleaning, packaging, sterilization.</li> <li>✚ Quality management system for manufacturing activities.</li> <li>✚ Regulatory files and survey: EC marking, 510(k), Master File (MAF)</li> </ul>

### EDUCATION

<b>Continuous training</b>	<p><b>2024 MD101</b> – Regulatory requirements of MDSAP jurisdictions (US, Canada, Australia, Brazil)</p> <p><b>2023 CPE</b> - Determination of molecular structure by mass spectrometry</p> <p><b>2022 BSI</b> - ISO 13485: 2016 clause by clause</p> <p><b>2021 Univ. Paris</b> - Toxicology Basics: Study of methodological mechanisms and approaches</p> <p><b>2020 BSI</b> - ISO 14971: 2019 Application of risk management to medical devices</p> <p><b>2019 LNE</b> - Clinical evaluation of medical devices (MEDDEV 2.7/1 Rev.4)</p> <p><b>2018 CPE</b> - Toxicology applied to health hazards</p> <p><b>2018 MD101</b> - 2017/745 regulation on medical devices</p> <p><b>2017 CEFIRA</b> - Toxicological evaluation of impurities in drug products</p> <p><b>2017 BSI</b> - Training of the trainer</p> <p><b>2016 LNE</b> - Internal and supplier audit according to ISO13485 and ISO19011</p> <p><b>2015 MEDIQUAL</b> - Application of usability engineering to medical devices (EN 62366)</p> <p><b>2014 TUV</b> - Biocompatibility of product and process (ISO 10993)</p> <p><b>2014 AFNOR</b> - Rules for drafting standards</p> <p><b>2013 COFRAC</b> - ISO/CEI 17025 Technical auditor of testing laboratories</p> <p><b>2012 CCI</b> - Strategy for SME – sales techniques</p> <p><b>2010 Consultant</b> - Management coaching</p> <p><b>2007 IFIS</b> - Materiovigilance management</p> <p><b>2006 LNE</b> - 510(k)</p> <p><b>2006 IDEE CONSULTING</b> - 21CFR US regulation for medical devices</p>
<b>Education</b>	<p><b>2024 Univ. Paris Cité</b> MASTER Toxicology and Ecotoxicology (THERV: Human toxicology, Evaluation of risks and vigilances)</p> <p><b>1999-2002 PhD</b> « Development of HA/TCP bone substitutes with antibiotic » (collaboration between MEDICAL GROUP and MATEIS lab of INSA Lyon)</p> <p><b>1994-1999 INSA Lyon</b> engineer school, specialization in materials</p>

### LANGUAGES

<b>Languages</b>	French: mother tongue	English: fluent
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## 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 Research, 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 medicine, 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)