

**Jean-Marc Wilkin, PhD**  
**Regulatory Affairs Professional**  
**Development, Licensing and Life-Cycle (CMC & non-clinical)**  
**Team Management**

Belgium | +32472808084 | [jean-marc.wilkin@bionregcmc.com](mailto:jean-marc.wilkin@bionregcmc.com) |  
[linkedin.com/in/jean-marc-wilkin](https://www.linkedin.com/in/jean-marc-wilkin)



### Profile

Highly accomplished and dedicated senior regulatory professional with more than 25 years of experience in research and development of biotechnical products in the pharmaceutical industry, supported by 10 years hands-on scientific knowledge acquired as a Researcher in several Public Institutions in Protein Engineering.

Demonstrated global CMC and non-clinical regulatory expertise in Biologics development, approval and life-cycle maintenance. Familiar with worldwide regulatory constraints and evolving environment, including knowledge of relevant global regulations and guidelines and interaction with Authorities.

With more than 15 years of experience in Team management, developed empowering and inclusive approach for leading diverse and remotely located regulatory Teams (up to 120 people). Experienced at building and leading high performing teams, including managing departmental budget and human resource. Comfortable working in a changing environment, dealing with unfamiliar situations.

### Expertise

- **Scientific Expertise:** Protein Engineering, Molecular Biology, Protein Biochemistry, Cell Biology in the field of Microbiology, Immunology and Vaccine manufacturing & testing.
- **Products Expertise:** deep knowledge with vaccines, therapeutic recombinant proteins, cell bank and viral vectors. Good knowledge with antibodies, mRNA-based products, cell & gene therapy and medical devices.
- **CMC Regulatory Expertise** spanning all product life-cycle stages:  
Specifically contributed to the development and licensing of several vaccines (e.g. Cervarix, H1N1 pandemic Flu vaccine, quadrivalent seasonal Flu vaccine, Shingrix) as well as to the worldwide license maintenance of the entire GSK vaccines portfolio (N = 25+ products), leading to submissions of hundreds of CMC variations every year. Interactions with worldwide Regulatory Authorities (e.g. FDA, EMA, PMDA, Korea MFDS, etc)
- **Worldwide regulatory guidance and requirements:** Deep knowledge of US and EU requirements and hands on experience of other countries such as Canada, Japan, China, South Korea, etc.
- **Non-clinical Regulatory Expertise:** Authoring of non-clinical M4, M2.4 and M2.6 e-CTD sections of Cervarix vaccine
- **Management of Change Control Process and Quality Systems:** release process, deviations & corrective and preventive actions, including regulatory inspections (FDA, EMA, Japan, Canada, etc.).
- **Change management:** supported 3 major organizational changes.
- **Objective-driven mindset with a can do attitude.** Strong sense of planning and prioritization, and the ability to work with all levels of management, influence others, solve problems and take tough decisions

### Professional Career

**BioNReg CMC Consulting**

**10/2023 – present**

**Founder, Senior Consultant, Regulatory Affairs**

Provision of scientific and strategic CMC regulatory advices as well as operational support to Biotech and Biopharma Companies for biologicals (vaccines, therapeutic recombinant proteins, antibodies, cell bank and viral vectors, RNA-based products) . Specific services provided:

- Scientific and CMC regulatory advice to help optimizing CMC and regulatory strategies during the entire product development, licensing and post-approval phases.
- Authoring and review of CMC dossiers – from clinical trial, to new marketing application to post approval variations and authorities briefing documents.

- Management support, including interim management, project management & connection and support to Technical Teams, issue & risk management
- Training/coaching of staff and/or Managers.

Main achievements:

- Provided regulatory advice on cell line characterization for immune treatment
- Authoring FTIH IND for rare disease (Fc Fusion protein), EMA Scientific Advice briefing document for innovative new antimicrobial treatment
- Provided training course on EU vaccine regulations

## **GlaxoSmithKline Biologicals, Belgium**

**09/1999-03/2023**

### **Senior Director, Head, CMC Vx mature Products, Global Regulatory Affairs**

**04/2021-03/2023**

Lead a team of 70 regulatory managers, experts and contingency workers remotely located at 6 different sites (US, Canada, Belgium, Italy, Germany, Singapore), in charge of the CMC life-cycle maintenance of all GSK vaccines licensed worldwide. Oversee complete submission and management of CMC life-cycle regulatory files across the entire GSK Vaccines portfolio, including change control process, regulatory compliance (both corrective & preventive actions), and product Line extensions. Managed departmental budget of 8 million £.

- Executed merger of Vaccines and Pharma GSK legacy organizations into a new integrated GSK regulatory organization building a new CMC Vaccine Mature Products Team responsible for the maintenance of the entire GSK licensed vaccine portfolio, and harmonization of ways of working across GSK regulatory units.
- Maintained all vaccine licenses (3000+) across the world through submission and approval of more than 150 primary variations per year, allowing business continuity of worldwide vaccine supply
- Delivered significant line extensions through Module 2 & 3 file preparation and review which increased / secured major vaccine market shares in the world
  - Achieved licensing Menveo Liquid vaccine in US and Brazil
  - Achieved license footprint extension Shingrix and Bexsero vaccines across the world (20+ countries)

### **Senior Director, Head CMC Excellence Global Regulatory Affairs**

**01/2015-04/2021**

Led a Team of regulatory managers and experts (n = 120) remotely located at 6 different sites (US, Canada, Belgium, Italy, Germany, The Netherlands), in charge of regulatory dossier preparations (CMC & facilities), submission & management of cross-products regulatory files, management of change control process and management of regulatory compliance (corrective & preventive actions) across the entire GRA Organization. Managed departmental budget of 12 million £.

- Executed merger of Novartis and GSK legacy organizations into a new integrated Organization (Sep 2015), building the CMC excellence department responsible for the writing of CMC and facility regulatory files required for the development and maintenance of entire integrated GSK vaccine portfolio.
- Contributed to the licensing of major new products (e.g. Mosquirix; Shingrix) through Module 2 and 3 file preparation and review
- Ensured authoring, review and approval of all Module 2 and 3 required for the maintenance of all GSK licensed vaccines as well as edition of all IND / IMPD / CTA dossiers required to support all GSK vaccine new product development.

### **Director, Head CMC and non-clinical Global Regulatory Affairs**

**09/2012-12/2014**

Led a Team of regulatory managers and experts (n = 70) remotely located at 4 sites (US, Canada, Belgium & Germany), in charge of regulatory dossier preparations (CMC, facilities, non-clinical, submission & management of cross-products regulatory files, management of change control process and management of regulatory compliance across the entire GRA Organization.

- Achieved re-organization of the GSK GRA organization (Sep 2012), building the CMC and non-clinical department responsible for the writing of non-clinical, CMC and facility regulatory files required for the development and maintenance of entire GSK vaccine portfolio.

- Ensured authoring, review and approval of all Module 2 and 3 required for the maintenance of all GSK licensed vaccines as well as edition of all IND/IMP/CTA dossiers (CMC and non-clinical sections) required to support all GSK vaccine new product development.
- Achieved worldwide regulatory registration of multi-products manufacturing sites
- Initiated and implemented major compliance programs for all GSK registered vaccines, including management of remediation variations/to ensure alignment between registered dossier details and Operational activities

#### **Prior Roles at GSK**

**09/1999-08/2012**

I joined GSK in September 1999 in the Regulatory Affairs CMC department and have had several roles of increasing responsibility till May 2007. A short description of these are provided below.

#### **Director, Technical Regulatory Affairs, Influenza Vaccines, North America**

**05/2007-08/2012**

Lead a Team of regulatory managers and experts (n = 10) remotely located at 3 sites (US, Canada, Belgium) in charge of regulatory dossier preparations (CMC, facilities, non-clinical) for all influenza vaccines manufactured out of Quebec Production Site, whether in development or already licensed. The Team was also acting as a local regulatory unit in Canada, interacting directly with Health Canada Authorities, covering all regulatory aspect related to Flu Products (Module 1 to 5, as appropriate).

- Achieved authoring, review and submission of Module 2, 3 and 4 required to ensure licensing of pandemic Arepanrix H1N1 vaccine in Canada, EU, Japan, Int'l and the unadjuvanted H1N1 vaccine in the US and Canada, including management of issues such as product aggregates and shelf-life as well as Arepanrix H5N1 vaccine in EU and Australia
- Achieved submission of clinical trial regulatory dossiers to support worldwide clinical development of new seasonal or pandemic Influenza vaccines

#### **Senior Technical Regulatory Affairs Manager (Cervarix Business Unit)**

**01/2005-05/2007**

Provided regulatory CMC advice to Technical Teams developing the Cervarix vaccine final commercial process, and prepared Module 3 and 4 dossier sections required for the registration in US, EU, Japan & International. Provided the required regulatory support required during the registration phase (response to Questions, meeting with Authorities, Inspections). Cervarix was filed in EU in 2006 and in US in 2007.

#### **US agent Liaison**

**03/2004-12/2004**

Achieved mapping of all the interactions between the regulatory Teams located in the US and Belgium. Proposed optimization & improvements in terms of ways of working and communication between the two Teams to ensure smoother US development and life-cycle regulatory activities.

#### **Technical Regulatory Affairs Scientist**

**09/1999-03/2004**

Achieved edition and submission of clinical and registration regulatory dossiers (technical and non-clinical part) worldwide (US, EU, International), including required follow-up (Form FDA 483, response to questions, etc.). Main focus was to provide CMC and Non-clinical advice to Phase 1-3 new product development Technical teams, as well as writing regulatory CMC dossiers required for the filing of INDs/IMP/CTAs, and a new MAA.

#### **Public Research Institutions, Belgium & Australia**

**09/1988-08/1999**

Before joining the Pharmaceutical industry in 1999, I worked 10 years in several Public Institutions/Universities as a Researcher in Protein Biochemistry/Protein engineering. The scientific hands-on expertise gathered during these 10 years covers Molecular Biology, Protein Biochemistry (protein expression, purification and physico-chemical characterization), Molecular Immunology, Cell Biology, Enzymology and Biochemistry of plant proteins.

Research Fields: Microbiology (antibiotic), Cellular Immunology (cytokines), Biochemistry (photosynthesis)

- Chargé de Recherches, Pasteur Institute of Brussels, Belgium **10/1997-08/1999**
- Chargé de Recherches, Fonds National de la Recherche Scientifique, Centre for Protein Engineering, University of Liège, Belgium **12/1995-09/1997**
- Post-Doctoral Fellow, Australian National University, Research School of Biological Sciences, Molecular Plant Physiology Group, Canberra, Australia **01/1994-11/1995**
- Ph D thesis in Biochemistry, Centre for Protein Engineering, Laboratory of Enzymology, University of Liège, Belgium **07/1989-12/1993**

- Mémoire de licence in Biochemistry (Master thesis in Biochemistry), Centre for Protein Engineering, Laboratory of Enzymology, University of Liège, Belgium . 09/1988-06/1989

## Education and Development

Regulatory Affairs for Combination Products (Drug/Device and Device/Drug), UK, Educo 2 days training	2024
Cell and Gene Therapy Volume 5, Belgium, Buz4Bio 2 days Conference	2024
mRNA Open Forum, Collaborating to pave the way for mRNA-base vaccines and therapeutic quality, 2 days webinar, USP Biologics	2024
Resilience Management, Belgium, GSK Training	2014
Developing People, Belgium, GSK Training	2014
Business Acumen, Developing your business skills, Belgium, GSK Training	2014
High Performing Teams, Belgium, GSK Training	2014
Managing Daily Performance, Belgium, GSK Training	2013
Practical Coaching in the workplace, Belgium, GSK Training	2013
Introduction to MBTI & Team analysis, Belgium, GSK Training	2013
The Pharma Mini MBA 3 days Training Course, London, Forum Management	2011
Needle-free and Auto Injector. Update on Technology and Application, London, Forum Management training	2002
Medical Immunology course, Free University of Brussels, Belgium	10/1998-01/1999
PhD in Biochemistry, University of Liège, Belgium	10/1989-12/1993
Teaching Degree, Biochemistry - University of Liège, Belgium	10/1988-09/1989
Master Degree in Biochemistry, Industry orientation - University of Liège, Belgium	10/1986-07/1989
Bachelor Degree in Chemical Sciences, University of Liège, Belgium	10/1984-09/1986

## Publications and Congresses

21 Publications

Active attendance to 3 international congresses (Posters)

See next pages for listing of publications and congresses

## Languages

**French:** Mother tongue

**English:** Listening & Reading C2, Speaking C2, Writing C2

## Publications

Bourguignon-Bellefroid, C., Hadonou, M. and **Wilkin, J.-M.** (1989) Site-directed mutagenesis of the extracellular penicillin-sensitive DD-carboxypeptidase of *Streptomyces* R61. *Archives Internationales de Physiologie et de Biochimie*, 97, p6

Frère, Jean-Marie, Joris, Bernard, Jacob-Dubuisson, Françoise, Matagne, Andre, Monnaie, Didier, Jamin, Marc, Hadonou, Médar, Bourguignon-Bellefroid, Catherine, Varetto, Louis, **Wilkin, Jean-Marc**, Dubus, Alain, Damblon, Christian, Adam, Maggy, Ledent, Philippe, De Meester, Fabien, Galleni, Moreno. (1991). Mechanism of Action of  $\beta$ -Lactamases and DD-Peptidases. *Bioorganic Chemistry in Healthcare and Technology*, edited by Pandit, U.K. and Alderweireldt, F.C. Plenum Press, New York, p. 161-170

Hadonou, Ayaovi, **Wilkin, Jean-Marc**, Varetto, Louis, Joris, Bernard, Lamotte-Brasseur, Josette, Klein, Daniel, Duez, Colette, Ghuysen, Jean-Marie, Frère, Jean-Marie. (1992). Site-directed mutagenesis of the *Streptomyces* R61 DD-peptidase. *European journal of biochemistry / FEBS*. 207. 97-102. 10.1111/j.1432-1033.1992.tb17025.x.

Bourguignon-Bellefroid, C, **Wilkin, J-M**, Joris, Bernard, Aplin, R, Houssier, C, Prendergast, F, Beeumen, Jozef, Ghuysen, JM & Frère, JM. (1992). Importance of the 2 tryptophan residues in the *Streptomyces* R61 exocellular DD-peptidase. *The Biochemical journal*. 282 (Pt 2). 361-7. 10.1042/bj2820361.

Jamin, Marc, **Wilkin, Jean-Marc**, Frère, Jean-Marie. (1993). A new kinetic mechanism for the concomitant hydrolysis and transfer reactions catalysed by bacterial DD-peptidases. *Biochemistry*. 32. 7278-85. 10.1021/bi00079a026.

**Wilkin, Jean-Marc**, Jamin, Marc, Joris, Bernard, Frère, Jean-Marie. (1993). Mechanism of action of DD-peptidases: role of asparagine-161 in the *Streptomyces* R61 DD-peptidase. *The Biochemical journal*. 293 ( Pt 1). 195-201. 10.1042/bj2930195.

**Wilkin, Jean-Marc**, Jamin, Marc, Damblon, Christian, Zhao, G, Joris, Bernard, Duez, Colette, Frère, Jean-Marie. (1993). The mechanism of action of DD-peptidases: the role of tyrosine-159 in the *Streptomyces* R61 DD-peptidase. *The Biochemical journal*. 291 (Pt 2). 537-44. 10.1042/bj2910537.

**Wilkin, Jean-Marc**, Dubus, Alain, Joris, Bernard, Frère, Jean-Marie. (1994). The mechanism of action of DD-peptidases: The role of threonin-299 and -301 in the *Streptomyces* R61 DD-peptidase. *The Biochemical journal*. 301 (Pt 2). 477-83. 10.1042/bj3010477.

Dubus, Alain, **Wilkin, Jean-Marc**, Raquet, Xavier, Normark, Staffan, Frère, Jean-Marie. (1994). Catalytic mechanism of active-site serine  $\beta$ -lactamases: role of the conserved hydroxy group of the Lys-Thr(Ser)-Gly triad. *The Biochemical journal*. 301 ( Pt 2). 485-94. 10.1042/bj3010485.

Granier, Benoit, Jamin, Marc, Adam, Maggy, Galleni, Moreno, Lakaye, Bernard, Zorzi, Willy, Grandchamps, Jacqueline, **Wilkin, Jean-Marc**, Fraipont, Claudine, Joris, Bernard, Duez, Colette, Nguyen-Disteche, Martine, Coyette, Jacques, Leyh-Bouille, Lina, Dusart, Jean, Christiaens, Léon, Frère, Jean-Marie, Ghuysen, Jean-Marie. (1994). Serine-type D-Ala-D-Ala peptidases and penicillin-binding proteins. *Methods in enzymology*. 244C. 249-266. 10.1016/0076-6879(94)44021-2.

Fanuel, Laurence, Granier, Benoit, **Wilkin, Jean-Marc**, Bellefroid-Bourguignon, Catherine, Joris, Bernard, Knowles, Jeremy, Komives, Elizabeth, Beeumen, Jozef, Ghuysen, Jean-Marie, Frère, Jean-Marie. (1994). The precursor of the *Streptomyces* R61 DD-peptidase containing a C-terminal extension is inactive. *FEBS letters*. 351. 49-52. 10.1016/0014-5793(94)00822-1.

Jamin, Marc, **Wilkin, Jean-Marc**, Frère, Jean-Marie. (1995). Bacterial DD-transpeptidases and penicillin. *Essays in biochemistry*. 29. 1-24.

Morell, Mats, **Wilkin, Jean-Marc**, Kane, Heather, Andrews, T. John. (1997). Side Reactions Catalyzed by Ribulose-bisphosphate Carboxylase in the Presence and Absence of Small Subunits. *The Journal of biological chemistry*. 272. 5445-51. 10.1074/jbc.272.9.5445.

Kane, Heather, **Wilkin, Jean-Marc**, Portis, Archie, Andrews, T. John. (1998). Potent Inhibition of Ribulose Bisphosphate Carboxylase by an Oxidized Impurity in Ribulose1,5-Bisphosphate. *Plant physiology*. 117. 1059-69.

**Wilkin, Jean-Marc**, Lamotte-Brasseur, Josette, Frère, Jean-Marie. (1998). The catalytic mechanism of DD-peptidases: Unexpected importance of tyrosine 280 in the transpeptidation reaction catalysed by the Streptomyces R61 DD-peptidase. *Cellular and molecular life sciences : CMLS*. 54. 726-32. 10.1007/s000180050200.

Y. Jacques, S. Minvielle, G. Müller-Newen, P.C. Heinrich, J. Grötzinger, F. Montero-Julian, H. Brailly, **J.M. Wilkin**, J. Content. (1998) The interleukin-11/receptor complex: rational design of agonists/antagonists and immunoassays potentially useful in human therapy. *Research in Immunology*. Volume 149, Issues 7–8, Pages 737-740

**Wilkin, J.-M.**, Soetaert, K., Stélandre, M., Buysens, P., Castillo, G., Demoulin, V., Bottu, G., Laneelle, M.-A., Daffe, M. and De Bruyn, J. (1999), Overexpression, purification and characterization of Mycobacterium bovis BCG alcohol dehydrogenase. *European Journal of Biochemistry*, 262: 299-307. <https://doi.org/10.1046/j.1432-1327.1999.00369.x>

Wang, Xiao-Ming, **Wilkin, Jean-Marc**, Boisteau, Olivier, Harmegnies, Dimitri, Blanc, Chrystel, Vandebussche, Paul, Montero-Julian, Félix, Jacques, Yannick, Content, Jean. (2002). Engineering and use of 32P-labeled human recombinant interleukin-11 for receptor binding studies. *European journal of biochemistry / FEBS*. 269. 61-8. 10.1046/j.0014-2956.2002.02622.x.

**Wilkin Jean-Marc** (2004) Penicillin-Binding Protein 4. Chapter 148, Pages 435-438 in *Handbook of Proteolytic Enzymes*, Volume 2, 2nd Edn

Potluri, L., Karczmarek, A., Verheul, J., Piette, A., **Wilkin, J.-M.**, Werth, N., Banzhaf, M., Vollmer, W., Young, K. D., Nguyen-Distèche, M., & den Blaauwen, T. (2010). Septal and lateral wall localization of PBP5, the major D,D-carboxypeptidase of Escherichia coli, requires substrate recognition and membrane attachment. *Molecular Microbiology*, 77(2), 300-23. <https://doi.org/10.1111/j.1365-2958.2010.07205.x>:

**Wilkin, Jean-Marc** (2013) Penicillin-Binding Protein 5, a Serine-type D-Ala-D-Ala Carboxypeptidase A, Chapter 763, Pages 3448-3451 in *Handbook of Proteolytic Enzymes*, Volume 3

## Congresses

1. International Meeting on: Trends microbial resistance to  $\beta$ -lactam antibiotics: molecular aspects and clinical implications, L'aquila and Rome, Italy, May 12-15 1990

Poster: Bourguignon-Bellefroid, C. and **Wilkin, J.-M.** Point mutations of two Trp and two Arg residues of the Streptomyces R61 DD-peptidase and their effect on the activity of the enzyme,

2. Fifth  $\beta$ -lactamase Workshop, Holy Island, United Kingdom, April 13-15 1992

Poster: **Wilkin, J.-M.**, Bourguignon-Bellefroid, C. and Hadonou, M. Study by site-directed mutagenesis of the catalytic mechanism of the Streptomyces R61 DD-peptidase.

3. International Symposium on: From Peptidoglycan Biosynthesis to Antibiotic Resistance. Present and Future. Liège, August 4-6 1997

Poster: **Wilkin J.-M.** The soluble DD-peptidase from Streptomyces R61, 25 years after.