



## Curriculum Vitae

Personal information **Wim Van Molle**

### Work experience

---

1. Employer: Sciensano
  - Start date: 05 2008
  - End date:
  - Position: Vaccine release responsible and quality assessor \_ Unit Manager Cellular and Molecular Biology & Biochemistry
  - Activities: Batch release of vaccines and assessment of quality part of MAA, variations, scientific advice, clinical trial applications GMP inspections.
  - Country: Belgium
2. Employer: Federal Agency for Medicinal and Health Products\_Department Registration
  - Start date: 08 2006
  - End date: 04 2008
  - Position: File manager
  - Activities: Delivery of marketing authorizations of medicinal products for human use
  - Country: Belgium
3. Employer: Ghent University, Department for Molecular Biomedical Research
  - Start date: 03 1999
  - End date: 12 2005
  - Position: Post doctoral investigator
  - Activities: Fundamental research on inflammation and cancer and training of new people
  - Country: Belgium

### Education and training

---

1. Subject: Ghent University, Department for Molecular Biomedical Research
  - Start date: 08 1994
  - End date: 03 1999
  - Qualification: PhD In Sciences, option Biotechnology
  - Organisation: Inflammation and cancer\_Fundamental research
  - Country: Belgium
2. Subject: Ghent University
  - Start date: 10 1990
  - End date: 07 1994
  - Qualification: Master in Biotechnology
  - Organisation: General scientific knowledge with focus on Biotechnology and molecular biology
  - Country: Belgium

### Additional information

---

#### Publications

##### Peer review Journals

- Brouckaert, P., Ameloot, P., Cauwels, A., Everaerd, B., Libert, C., Takahashi, N., Van Molle, W. & Fiers, W. Receptor selective mutants of tumour necrosis factor in the therapy of cancer: Preclinical studies. *Circ. Shock* 43, 185 190, 1994.
- Libert, C., Van Molle, W., Brouckaert, P. & Fiers, W. □1 Antitrypsin inhibits the lethal response to TNF in mice. *J. Immunol.* 157, 5126 5129, 1996. • Libert, C., Van Molle, W., Brouckaert, P. & Fiers, W. Platelet activating factor is a mediator in tumor necrosis factor/galactosamine induced lethality. *J. Inflammation* 46, 139 143, 1996.
- Brouckaert, P., Libert, C., Cauwels, A., Everaerd, B., Van Molle, W., Ameloot, P., Gansemans, Y., Grijalba, B., Takahashi, N., Truong, M. J., Van Leuven, P. & Fiers, W. Inhibition of and sensitization to the lethal effects of tumor necrosis factor. *J. Inflammation* 47, 18 26, 1996. • Van Molle, W., Libert, C., Fiers, W. & Brouckaert, P. □1 Acid glycoprotein and □1 antitrypsin inhibit TNF induced but not anti Fas induced apoptosis of hepatocytes in mice. *J. Immunol.* 159, 3555 3564, 1997.
- Libert, C., Wielockx, B., Grijalba, B., Van Molle, W., Brouckaert, P., Kremmer, E., Colten, H.R. & Fiers, W. The role of complement activation in tumor necrosis factor induced lethal hepatitis. *Cytokine* 11, 617\_625 1999.
- Van Molle, W., Brouckaert, P. & Libert, C. Caspase 1 is not involved in experimental hepatitis in mice. *FEBS Lett.*, 445, 115\_118, 1999.
- Van Molle, W., Denecker, G., Rodriguez, I., Brouckaert, P., Vandenabeele, P. & Libert C. Activation of Caspases in Lethal Experimental Hepatitis is Prevented by Protective Acute Phase Proteins. *J. Immunol.* 163, 5235\_5241, 1999.
- Van Molle, W., Vanden Berghe, J., Brouckaert, P. & Libert, C. Tumor necrosis factor induced lethal hepatitis: Pharmacological intervention with verapamil, tannic acid, picotamide and K76COOH. *FEBS Lett* 467, 201\_205, 2000.
- Van Molle, W., Hocheplid, T., Brouckaert, P. & Libert, C. The major acute\_phase protein, serum amyloid P component, in mice is not involved in endogenous resistance against tumor necrosis factor alpha\_induced lethal hepatitis, shock, and skin necrosis. *Infect. Immun.* 68, 5026\_5029, 2000.

- Hochepped, T., Van Molle, W., Berger, F.G., Baumann, H. & Libert, C. Involvement of the acute phase protein  $\alpha_1$  acid glycoprotein in nonspecific resistance to a lethal Gram-negative infection. *J. Biol. Chem.* 275, 14903-14909, 2000.
  - Cauwels, A., Van Molle, W., Janssen, B., Everaerd, B., Huang, P., Fiers, W. & Brouckaert, P. Protection against TNF-induced lethal shock by soluble guanylate cyclase inhibition requires functional inducible nitric oxide synthase. *Immunity* 13, 223-231, 2000.
  - Wielockx, B., Hochepped, T., Staelens, J., Van Molle, W., Brouckaert, P., & Libert, C. Detection, characterisation and purification of a murine liver factor capable of desensitising towards the lethal activity of tumour necrosis factor. 2001. *Cytokine*. 15:59-65.
  - Dick, J.M., Van Molle, W., Libert, C., Lefebvre, R.A. Antisense knockdown of inducible nitric oxide synthase inhibits the relaxant effect of VIP in isolated smooth muscle cells of the mouse gastric fundus. 2001. *Br J Pharmacol*. 134:425-433.
  - Dick, J.M.C., Van Molle, W., Brouckaert, P. & Lefebvre, R.A. Relaxation by vasoactive intestinal polypeptide in the gastric fundus of nitric oxide synthase-deficient mice. 2002. *J. Physiol*. 538:133-143.
  - Van Molle, W., Wielockx, B., Mahieu, T., Takada, M., Taniguchi, T., Sekikawa, K., & Libert, C. HSP70 protects against TNF-induced lethal inflammatory shock. 2002. *Immunity*. 16:885-895.
  - Van Molle, W., & Libert, C. Bilirubin release induced by tumor necrosis factor in combination with galactosamine is toxic to mice. 2003. *Cytokine*, 23:91-100
  - De Bosscher, K., Vanden Berghe, W., Beck, I., Van Molle, W., Hennuyer, N., Hapgood, J., Libert, C., Louw, A., Staels, B. and Haegeman, G., A novel, fully dissociated compound of plant origin for inflammatory gene repression. 2005. *PNAS*. 102:15827-15832.
  - Van Molle, W., & Libert, C. How Glucocorticoids control their own strength and the balance between pro- and anti-inflammatory mediators. 2005. *Eur. J. Immunol*. 35:3396-3399.
  - Van Molle, W., Van Roy, M., Van Bogaert, T., Dejager, L., Van Lint, P., Vanlaere, I., Sekikawa, K., Kollias, G. & Libert C. Protection of zinc against TNF-induced lethal inflammation depends on HSP70 and allows safe antitumor therapy. 2007. *Cancer Reserach*. 67:7301-7307.
  - Vanhooren V., Liu X.E., Desmyter L., Fan Y.D., Vanwalleghem L., Van Molle W., Dewaele S., Praet M., Contreras R., Libert, C & Chen C. Over-expression of heat shock protein 70 in transgenic mice causes growth retardation and early death. 2008. *Rejuvenation Res*. 11, 1013-1020.
  - Vipond, C., Mulloy, B., Rigsby, P., Burkin, K., Bolgiano, B., and MenC IS Working Group. Evaluation of a candidate International Standard for Meningococcal Group C polysaccharide. 2012. *Biologicals*. 40, 353-363.
  - Bekeredjian\_Ding, I., Van Molle, W., Baay, M., and Neels, on behalf of speakers and session chairs. Human Challenge Trial Workshop: Focus on Quality Requirements for Challenge Agents, Langen, Germany, October 22, 2019. 2020. *Biologicals*, 66, 53-61.
  - Bekeredjian\_Ding, I., Trouvin, J.-H., Depraetere, H., La, C., E Suvarnapunya, A., Bell, A., Mann, A., Meij, P., Bethony, J.M., Schellhaas, L., Nazziwa, W.B., Karikari\_Boateng, E., Prachumsri, J.S., Salmikangas, P., Smith, S., Stjärnkvist, P., Van Molle, W., Baay, M., and Neels, P. Controlled Human Infection Studies: Proposals for guidance on how to design, develop and produce a challenge strain. 2021. *Biologicals*, 74, 16-23.
  - \* Marcel H.N. Hoefnagel, Paul Stickings, Dean Smith, Carmen Jungbäck, Wim Van Molle & Lorenzo Tesolin. Rational arguments for regulatory acceptance of consistency testing: benefits of non-animal testing over in vivo release testing of vaccines. 2023. *Expert Review of Vaccines*.
  - \* Dierick, J.F., Halder, M., Jungbaeck, C., Lorenz, J., Préaud, J.-M., Riou, P., Tesolin, L., Uhlrich, S., Van Molle, W., and Vandeputte, J. The consistency approach for the substitution of in vivo testing for the quality control of established vaccines: practical considerations and progressive vision. 2023. *Open Research Europe*.
  - \* Vermeulen M, Feck I, Francotte A, Hassall L, Tesolin L, Van Molle W, Pizzato R, Laurent T, Hoebreck C, Stickings P, Doby A. Development of a multiplex-based immunoassay for the characterization of diphtheria, tetanus and acellular pertussis antigens in human combined DTaP vaccines. 2023. *J Immunol Methods*.
  - \* Elham Ramin, Antonio Gaetano Cardillo, Reinhard Liebers, Johannes Schmölder, Eric von Lieres, Wim Van Molle, Bastian Niebel, Laurent Natalis, Irina Meln, Mónica Perea-Vélez, Didier Clénet, John Bagterp Jørgensen, Bernt Nilsson, Daniel G. Bracewell and Krist V. Gernaey. Accelerating vaccine manufacturing development through model-based approaches: current advances and future opportunities. 2024. *Current Opinion in Chemical Engineering* 43:100998
  - \* Nicoletta Corti, Christopher Chiu, Rebecca J. Cox, Clarisse Demont, Jeanne-Marie Devaster, Othmar G. Engelhardt, Andrew Gorringer, Khaole Hassan, Marcel Hoefnagel, Ingrid Kamerling, Oleg Krut, Chelsea Lane, Reinhard Liebers, Catherine Luke, **Wim Van Molle**, Sandra Morel, Pieter Neels, Meta Roestenberg, Michelle Rubbrecht, Wiep Klaas Smits, Daniel Stoughton, Kawsar Talaat, Maria J.G.T. Vehreschild, Adrian Wildfire, Irina Meln, Ole F. Olesen. Regulatory workshop on challenge strain development and GMP manufacture – A stakeholder meeting report. 2024. *Biologicals* 85: 101746
  - \* Euzebiusz Jamrozik, Katherine Littler, Irina Meln, **Wim Van Molle**, Sandra Morel, Ole F. Olesen, Michelle Rubbrecht, Shobana Balasingam, Pieter Neels. Ethical approval for controlled human infectious model clinical trial protocols – A workshop report. 2024. *Biologicals* 85: 101748.
  - \* Nancy C Sajjadi, Ryan Brady, Carmen Jungbäck, Laurent Mallet, Catherine Milne, Sandra Prior, Gayle Pulle, Peter Rigsby, Tim Schofield, Richard Siggers, Dean Smith, Paul Stickings, Sylvie Uhlrich, **Wim Van Molle**, Angela Walker, Tong Wu, Tiequn Zhou, Maria Baca-Estrada. Maintaining the quality of vaccines through the use of standards: Current challenges and future opportunities. 2024. *Biologicals* 86: 101756.
  - \* Irina Meln, Wim Van Molle, Mónica Perea Vélez, Greger Abrahamsen, Koen Brusselmans, Eric Calvosa, Antonio Gaetano Cardillo, Didier Clénet, Caroline Forestieri, Krist V. Gernaey, Marcel Hoefnagel, John Bagterp Jørgensen, Pierre Lebrun, Laurent Natalis, Bernt Nilsson, Volker Öppling, Julius Carl Pollinger, Andrea C.M.E. Rayat, Daniel Reem, Michelle Rubbrecht, Johannes Schmölder, Timothy Schofield, Dean Smith, Stefanie Timmins, Eric von Lieres, Mats Welin and Daniel G. Bracewell. Advancing regulatory dialogue: In silico models for improved vaccine biomanufacturing - an expert meeting report. 2025. *Vaccine* 56: 127170.
- Abstract
- Brouckaert, P., Ameloot, P., Cauwels, A., Everaerd, B., Libert, C., Takahashi, N., Vandenabeele, P., Van Molle, W. & Fiers, W. Two receptor types for TNF: Implications for therapy and pathogenesis. Abstract. Conference on Clinical Interest of Cytokines. Brussels (Belgium), April 21, 1994.
  - Everaerd, B., Cauwels, A., Van Molle, W., Grijalba, B., Truong, M. J., Ameloot, P., Libert, C., Takahashi, N., Brouckaert, P. & Fiers, W. A central role for vasculature mediated processes in TNF induced lethal toxicity. Abstract. 7th Endothelial Symposium. Antwerpen (Belgium), May 31, 1995. In "Abstracts", p. 32, 1995.

- Brouckaert, P., Ameloot, P., Cauwels, A., Everaerd, B., Libert, C., Takahashi, N., Truong, M. J., Van Molle, W. & Fiers, W. Tumor necrosis factor and its mutants as potential anti cancer therapy. Abstract. 19th International Congress of Chemotherapy. Montréal (Canada), July 16 21, 1995. *Can. J. Infect. Dis.* 6 (suppl. C), 259C, No. 0452, 1995.
- Brouckaert, P., Ameloot, P., Cauwels, A., Everaerd, B., Grijalba, B., Libert, C., Takahashi, N., Truong, M. J., Van Molle, W. & Fiers, W. Preclinical studies on TNF: Strategies to reduce in vivo toxicity. Abstract. EC Biotech Meeting "In Vitro Immunotoxicology". Gent (Belgium), November 16 18, 1995.
- Van Molle, W., Everaerd, B., Cauwels, A., Brouckaert, P. & Fiers, W. Optimization and application in TNF related models of a method to estimate NO production in vivo. *Arch. Physiol. Biochem.* 103, B28, 1995.
- Brouckaert, P., Cauwels, A., Everaerd, B., Grijalba, B., Van Molle, W., Ameloot, P., Libert, C., Takahashi, N., Truong, M. J. & Fiers, W. Mechanisms of sensitization by infections towards tumour necrosis factor induced SIRS. Abstract. 16th International Symposium on Intensive Care and Emergency Medicine. Brussels (Belgium), March 19 22, 1996. *Intensive Care Med.* 22 (suppl. 1), S28, 1996.
- Brouckaert, P., Cauwels, A., Everaerd, B., Grijalba, B., Van Molle, W., Ameloot, P., Gansemans, Y., Libert, C., Takahashi, N., Truong, M. J., Van Leuven, P. & Fiers, W. Mechanisms of sensitization to the effects of TNF. Abstract. 6th International TNF Congress. Faliraki (Rhodes, Greece), May 8 12, 1996. *Eur. Cytokine Netw.* 7, 157, No. L4, 1996.
- Libert, C., Van Molle, W., Ameloot, P., Everaerd, B., Grijalba, B., Takahashi, N., Truong, M. J., Van Leuven, P., Gansemans, Y., Fiers, W. & Brouckaert, P. Protection against TNF induced lethal shock by acute phase proteins. Abstract. 6th International TNF Congress. Faliraki (Rhodes, Greece), May 8 12, 1996. *Eur. Cytokine Netw.* 7, 300, No. 229, 1996.
- Van Molle, W., Libert, C., Everaerd, B., Grijalba, B., Gansemans, Y., Ameloot, P., Takahashi, N., Truong, M. J., Hochepped, T., Fiers, W. & Brouckaert, P.  $\alpha$ 1 Acid glycoprotein (AGP) inhibits TNF specific apoptosis induction in hepatocytes, but not in hepatoma tumour cell lines. Abstract. Meeting of the Belgian Association for Cancer Research. Liège (Belgium), January 25, 1997. In "Abstracts", No. 64, 1997.
- Libert, C., Van Molle, W., Hochepped, T., Ameloot, P., Everaerd, B., Gansemans, Y., Grijalba, B., Takahashi, N., Truong, M. J., Fiers, W. & Brouckaert, P. Inhibition of tumor necrosis factor induced liver toxicity and lethality by the acute phase proteins  $\alpha$ 1 acid glycoprotein and  $\alpha$ 1 antitrypsin. Abstract. 4th International Congress on the Immune Consequences of Trauma, Shock and Sepsis. Mechanisms and Therapeutic Approaches. München (Germany), March 4 8, 1997. *Shock* 7, Suppl., 65, No. 256, 1997.
- Brouckaert, P., Cauwels, A., Everaerd, B., Grijalba, B., Van Molle, W., Ameloot, P., Gansemans, Y., Libert, C., Takahashi, N., Truong, M. J. & Fiers, W. Sensitization to and inhibition of the lethal effects of TNF in infected mice. Abstract. 4th International Congress on the Immune Consequences of Trauma, Shock and Sepsis. Mechanisms and Therapeutic Approaches. München (Germany), March 4 8, 1997. *Shock* 7, Suppl., 83, No. 328, 1997.
- Gansemans, Y., Cauwels, A., Everaerd, B., Grijalba, B., Van Molle, W., Stanssens, P., Fiers, W. & Brouckaert, P. Soluble guanylate cyclase: An NO activated key mediator of TNF induced hypotension. Abstract. FEBS Special Meeting on Cell Signalling Mechanisms. Amsterdam (The Netherlands), June 29 July 3, 1997. In "Abstracts", No. C8 003, 1997.
- Van Molle, W., Denecker, G., Grijalba, B., Van de Craen, M., Libert, C., Vandenabeele, P. & Brouckaert, P. Involvement of caspases in experimental hepatitis. Abstract. 7th International TNF Congress. Hyannis, MA (USA), May 17 21, 1998. *J. Interferon Cytokine Res.* 18, A113, No. 5.55, 1998.
- Gansemans, Y., Cauwels, A., Everaerd, B., Grijalba, B., Van Molle, W., Stanssens, P., Fiers, W. & Brouckaert, P. Soluble guanylate cyclase: A nitric oxide activated heme protein as a key mediator of inflammatory hypotension. *Arch. Physiol. Biochem.* 106, B7, 1998.
- Van Molle, W., Libert, C., Hochepped, T., Wielockx, B., Grijalba, B., Ameloot, P., Everaerd, B., Takahashi, N., Fiers, W. & Brouckaert, P. The acute phase proteins  $\alpha$ 1 acid glycoprotein and  $\alpha$ 1 antitrypsin are inhibitors of TNF but not anti Fas induced apoptosis of hepatocytes in mice. *Arch. Physiol. Biochem.* 106, B20, 1998.
- Wielockx, B., Grijalba, B., Van Molle, W., Brouckaert, P., Kremmer, E., Fiers, W., Colten, H. & Libert, C. Complement activation in tumor necrosis factor induced lethal hepatitis. *Arch. Physiol. Biochem.* 106, B22, 1998. • Van Molle, W., Denecker, G., Brouckaert, P., Vandenabeele, P. & Libert, C. Activation and inhibition of caspases in TNF induced lethal hepatitis. Abstract. Meeting of the Belgian Association for the Study of Cancer. Antwerp (Belgium), January 30, 1999. In "Abstracts", No. 46, 1999.
- Van Molle, W., Wielockx, B., Hochepped, T., Staelens, J. & Libert, C. Research into the endogenous protecting mechanisms of desensitisation and tolerisation. Abstract 8th International Congress on Tumor Necrosis Factor and related cytokines. 14\_18/5/2000, Trondheim, Norway.
- Van Molle, W., Hochepped, T., Wielockx, B., Staelens, J., & Libert, C. Identification of novel endogenous protecting genes using macro\_arrays for differential gene induction. 2001. *Inflamm. Res.* 50 (Suppl. 3):S189. Abstract 5th International Congress on inflammation, 22\_26/09/2001, Edinburgh, Scotland.
- Van Molle, W., Wielockx, B., Mahieu, T., Takada, M., Taniguchi, T., Sekikawa, K. & Libert, C. A role for HSP70 in heat shock mediated protection against TNF induced lethal inflammatory shock. Abstract 6th biennial meeting on Molecular Chaperones and the heat shock response. 1\_5/5/2002. Cold Spring Harbor, NY, USA.
- Van Molle, W., Vandenabeele, A., Moens, K., Sekikawa, K., Jäättelä, M., & Libert, C. HSP70 and glucocorticoids form a consortium in preventing TNF induced lethal inflammatory shock. Abstract 1st international congress on Stress Responses in Biology and Medicine. 10\_14/9/2003. Quebec, Canada.
- Van Molle, W., Sekikawa, K., Jäättelä, M., Kollias, G., & Libert, C. HSP70 has strong in vivo anti\_inflammatory capacities: lessons from hsp70.1 knockout and hsp70 transgenic mice. Abstract 7th biennial meeting on Molecular Chaperones and the heat shock response. 5\_9/5/2004. Cold Spring Harbor, NY, USA.
- De Bosscher, K., Vanden Berghe, W., Beck, I.M.E., Van Molle, W., Louw, A., Libert, C., Hapgood, J., & Haegeman, G. A novel, NF\_κB selective, fully dissociated compound of plant origin for inflammatory gene repression. Abstract CASCADE summer School on Nuclear Hormone Receptors, Ecole Normale Supérieure de Lyon. 13\_17/9/2004. Lyon, France
- Van Molle, W., Maes, A., Ribaucour, F. & Waeterloos G. Implementation over the past 20 years of the 3R's principle for batch release at the Scientific Institute of Public Health, Belgium (IPH). Abstract EDQM meeting: Quality of medicines in a globalised world: dreams and reality. 14\_15/10/2010. Prague, Czech Republic.
- Van Molle W., Brusselmans, K., Tesolin L. & Waeterloos, G. Regulatory issues regarding manufacture and control of vaccine adjuvants. The EU situation. Abstract MVA2013 meeting. Modern vaccines/adjuvants formulation. Impact on future development. 15\_17/05/2013. CHUV, Lausanne, Switzerland.
- Van Molle W., Tesolin, L., Brusselmans, K. and Waeterloos, G. Batch release of vaccines in Europe: from method transfer to first commercial batch available on the market. Straightforward approach that requires a proactive mindset of the manufacturer. PDA Europe Conference Vaccines. Featuring WHO on Challenges in Vaccines Supply to

Developing Countries. 30/11\_2/12/2015, Berlin, Germany.

- Van Molle W., Tesolin, L., and Waeterloos, G Batch release of vaccines in Europe: from method transfer to first commercial batch available on the market. Straightforward approach that requires a proactive mindset of the manufacturer. Abstract conference EDQM & European Pharmacopoeia: State\_of\_the\_Art Science for Tomorrow's Medicines. 19\_20/06/2019, Strasbourg, France.

- \* Van Molle W., Brusselmans K. and Tesolin L. Regulatory expectations on the use of vaccine reference standards for maintaining product quality. Abstract IABS conference on "Maintaining the quality of vaccines through the use of standards: Current challenges and future opportunities." 21-22 June 2023, Ottawa, Canada.

**Projects** Inno4Vac IMI \_2 project, ST\_2 and ST4

## Memberships

Memberships

- \* Temporary expert WHO

- \* Group 15 Member Ph. Eur.

- \* mRNAVAC WP member Ph Eur.

- \* Oral presentations

- Application of TNF in a systemic cancer treatment by selectively inhibiting the dose\_limiting toxicities. Annual meeting Belgian association for cancer research. 24/1/98. VUB. Brussels, Belgium.

- In vivo studies on apoptosis in the liver. IUAP\_PA1 meeting. 9/98. ULB. Brussels, Belgium.. • TNF\_induced liver toxicity: what are the mechanisms and how can we prevent it ? Symposium van de European Society of Biochemistry and Pharmacology: "Mechanisms of cell death in tissue degeneration". 26\_28/9/99. Otzenhausen. Germany.

- Identification of novel endogenous TNF protecting genes using macro\_arrays for differential gene induction. 5th World Congress on Inflammation. 22\_26/9/01. Edinburgh. Scotland.

- HSP70 inhibits TNF\_induced lethal inflammation: a role for glucocorticoids? Biomedizinische Vorträge in Heidelberg, 24/03/03, DKFZ, Heidelberg, Germany.

- HSP70 and glucocorticoids form a consortium in preventing TNF\_induced lethal inflammatory shock. 49. Jahrestagung der Gesellschaft für Thrombose\_ und Hämostaseforschung e.V. 23\_26/2/2005. Mannheim. Germany.

- The life\_saving axis HSP70\_glucocorticoid receptor in acute inflammatory shock. 49. Jahrestagung der Gesellschaft für Thrombose\_ und Hämostaseforschung e.V. 23\_26/2/2005. Mannheim. Germany.

- Update on strategies for Synflorix Vaccine. Annual OMCL meeting, 25\_29/5/2009, Vienna, Austria.

- Hib vaccine long term stability result. Annual OMCL meeting, 17\_21/5/2010, Split, Croatia.

- Testing and release of synflorix monovalent conjugated bulks update after 1 year of a complex vaccine with complex testing. Annual OMCL meeting, 17\_21/5/2010, Split, Croatia

- Regulatory issues regarding manufacture and control of vaccine adjuvants. The EU situation. MVA2013 meeting. Modern vaccines/adjuvants formulation. Impact on future development. 15\_17/05/2013. CHUV, Lausanne, Switzerland.

- Possible presence of particles in MMR vaccines detected by Egyptian OMCL resolved by interaction with Belgian OMCL and manufacturer. General Biologicals Session June 11, 2013, Annual OMCL Meeting, 10\_14 June 2013, Helsinki, Finland

- European accreditation bodies require the OMCL participation in PTS independently of the performance of blind testing: a trend or a reality?. General Session June 11, 2013, Annual OMCL Meeting, 10\_14 June 2013, Helsinki, Finland.

- Hexyon: a fully liquid hexavalent vaccine (soon) on the market. OCABR Vaccines session, June 13, 2013., Annual OMCL Meeting, 10\_14 June 2013, Helsinki, Finland.

- The Key to Success in R&D: Into the Minds of the Quality Assessors. Biological Production Forum 2015, 2\_4/03/2015, Düsseldorf, Germany.

- Vaxelis (PR5I): another fully liquid hexavalent vaccine on the EU market in 2016. OCABR Vaccines session, June 01, 2015, Annual OMCL Meeting, 01\_05 June 2015, Brussels, Belgium.

- Batch release of vaccines in Europe: from method transfer to first commercial batch available on the market. Straightforward approach that requires a proactive mindset of the manufacturer. PDA Europe Conference Vaccines. Featuring WHO on Challenges in Vaccines Supply to Developing Countries, 30/11\_2/12/2015, Berlin, Germany.

- Regulatory Position on Specification Settings. PDA Europe Conference Vaccines. Featuring WHO on Challenges in Vaccines Supply to Developing Countries, 30/11\_2/12/2015, Berlin, Germany.

- Method Transfer of the Hexavalent Vaccine Vaxelis: a Bumpy Road With a Happy Ending. OCABR Vaccines session, May 18, 2017, Annual OMCL Meeting, 15\_19 May 2017, Budapest, Hungary.

- Approaching EMA and National regulatory authorities: who, when and how. 2017 Vaccines Bioprocess Development & Commercialization Workshop, 26\_29 June 2017, Cambridge, MA, USA,

- Setting specifications for Biologicals. Points to consider from simple to complex. Case study for viral vectored vaccines. 2017 BioMAN Workshop on Setting Specifications for Biotherapeutic Products, 12 September 2017, Cambridge, MA, USA.

- Adjuvants for vaccines, A need for quality time? COST regulatory workshop on adjuvants, 23\_24 September 2019, Belgrade, Serbia.

- How, where and when to get and/ask for information and help. COST regulatory workshop on adjuvants, 23\_24 September 2019, Belgrade, Serbia.

- The EMA PRIME procedure in an accelerated assessment environment for vaccine licensure: Experiences from quality (CMC) assessors. A case study for Ebola vaccine. 2020 PDA EUROPE \_ Driving Biopharmaceutical Innovations & Sustainability BioManufacturing, 22\_23 September 2020. Virtual meeting.

- Panel discussion on IABS Webinar on CHIM and COVID19, SARS CoV\_2 CHIM, 23 June 2020, Webinar.

- Panel discussion on CMC in 'Risk\_ based strategies to support current health emergency. World Vaccine Conference (EU), 20 October 2020, Web based.

- Round table discussion. Human Infection Studies Considerations on manufacturing of challenge agents\_ viruses (SARS\_CoV\_2/COVID\_19) and parasites as examples. A Joint Wellcome Trust/HIC\_Vac, hVIVO and IABS webinar, 31 January 2021. Webinar.
- Sustainability in Quality Control of Vaccines: Applying the 3R's principle and implementing the 4th R. 2022 PDA Biomanufacturing Conference "Biopharmaceutical Solutions to Prepare for Healthcare Challenges", 20\_21 September 2022, Amsterdam, The Netherlands.
- Round table Q&A on Vaccine Lifecycle management. 2022 PDA Biomanufacturing Conference "Biopharmaceutical Solutions to Prepare for Healthcare Challenges", 20\_21 September 2022, Amsterdam, The Netherlands.
- Round table Q&A on sustainability and digitalization. 2022 PDA Biomanufacturing Conference "Biopharmaceutical Solutions to Prepare for Healthcare Challenges", 20\_21 September 2022, Amsterdam, The Netherlands.
- \* Regulatory expectations on the use of vaccine reference standards for maintaining product quality. 2023. IABS conference on "Maintaining the quality of vaccines through the use of standards: Current challenges and future opportunities." 21-22 June 2023, Ottawa, Canada.
- \* The IMI Inno4Vac project: a public-private partnership focussing on Innovations to accelerate vaccine development and manufacture. 2023 PDA Biomanufacturing Conference "Agility and Biomanufacturing Excellence to Meet Patients' Needs", 12-13 September 2023, Seville, Spain.
- \* Closing Panel Discussion. 2023 PDA Biomanufacturing Conference "Agility and Biomanufacturing Excellence to Meet Patients' Needs", 12-13 September 2023, Seville, Spain

## Other Relevant Information