
Magalie Wasem Tréguer

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Executive Summary

- International legal counsel trained at a leading global law firm with broad transactional, corporate and commercial experience
- Extensive expertise in regulatory and research and development legal matters having led the global clinical operations support at a leading biotech and advised on complex clinical, regulatory and pharmacovigilance legal matters
- Robust expertise in the design and implementation of a global Compliance program in the pharmaceutical sector
- Sixteen years of experience as team leader or ad hoc project leader in Legal and Compliance departments
- Has set up her own consulting company in 2015 offering tailored legal and compliance advice to the life sciences industry

09/2015 – Now

Pharma Law Solutions, Zürich area

Managing Partner

Offering tailored legal and compliance advice to the pharmaceutical, biotechnology and medical device industry

10/2013 – 08/2015

Biogen Idec International GmbH, Zug

*Senior Director, Compliance. Heading the Compliance Department for Europe and Canada
Member of the European Leadership Team*

Responsible for the development, coordination and implementation of the Biogen Idec Corporate Compliance Program in Region Europe. Managing a team of six Compliance officers and reporting to the Chief Compliance Officer

08/2008 – 10/2013

Biogen Idec International GmbH, Zug

Director, Legal

Global lead for clinical operations and international regulatory and pharmacovigilance matters

Advising on global research and development activities and clinical operations in seventy countries as well as ex-US medical affairs, regulatory and drug safety matters. Manager of two paralegals supporting Research & Development (R&D) activities

11/2004 – 08/2008

Biogen Idec International GmbH, Zug

Senior Manager, Legal promoted to Associate Director, Legal. Commercial lawyer supporting the business within a broad territory

Responsible for on-going legal support to the Iberian, Benelux, French, Canadian affiliates and for the distribution markets in a vast number of countries. Lead advisor on anti-trust and competition matters ex-US

01/2001 – 11/2004

Freshfields Bruckhaus Deringer, Paris

Corporate lawyer in the Mergers & Acquisitions Department

Job description and professional achievements

10/2013 – 08/2015

Biogen Idec International GmbH

*Senior Director, Compliance. Heading the Compliance Department for Europe and Canada
Member of the European Leadership Team*

Key Responsibilities

- Managing the team of six senior Compliance officers responsible for the various clusters of countries in Europe and Canada and ensuring key partnership and alignment with the standards and governance national roles existing across Europe
- Compliance head, member of the Biogen Idec European leadership team and representing the company at EFPIA Compliance key meetings
- Customizing and implementing the global Compliance program in Europe and Canada
- Establishing robust monitoring standards to ensure proactive risk awareness and high levels of legal compliance
- Ensuring creation and on-going updates of the relevant policies and standard operating procedures at regional and national level and relevant training to enhance governance standards
- Offering strategic advice with respect to the roll out of the program
- Managing department budget

Key Achievements

- Fostering the credibility of the Compliance function and establishing a strong dialogue between the global function and the regional operations
- Ensuring the cohesion of the team and close partnership with Legal and Standards and Governance departments
- Leading a proactive Compliance and Governance committee overseeing the challenges across Europe and making aligned regional decisions
- Ensuring roll out of key compliance global and regional projects such as transparency EFPIA project, nurse services project, advisory boards project etc.

08/2008 – 10/2013

Biogen Idec International GmbH, Zug

Director, Legal

Global lead for clinical operations and international regulatory and pharmacovigilance matters

Key responsibilities

- Managing the team of paralegals responsible for the daily advice to the research and development operational teams
- Building a robust repository of reference templates and legal opinions to ensure more efficient knowledge management
- Advising on complex research and development challenges involving legal, ethical, good clinical practice and data privacy issues
- Managing all legal aspects of the relationship with CROs, ethics committees and clinical sites
- Advising on pharmacovigilance, regulatory development and big data matters
- Leading role at the CT Legal (Clinical Trial Legal) inter-company forum hosted by Sidley Austin

Key Achievements

- Awarded the Biogen Idec Leadership Price in 2009
- Created best in class knowledge management platform with customized agreements and client friendly guidance to ensure autonomous speedy negotiations with the sites
- Designed comprehensive CRO negotiation guidelines to ensure the right levels of company controls while ensuring efficient negotiations
- Led the creation of the secondary research policy
- Led discussions with EMA on clinical data transparency

- 11/2004 – 08/2008 **Biogen Idec International GmbH, Zug**
Associate Director, Legal. Commercial lawyer supporting the business within a broad territory
- Key responsibilities
- Ensuring dedicated legal support to a number of affiliates (Spain, Portugal, France, Benelux, Canada)
 - Lead lawyer for the distribution business in Europe, Middle East and Latin America
 - Creating the new affiliates in Latin America (Brazil, Mexico, Argentina) and ensuring a smooth transition under the distribution agreements
 - Anti-trust responsibility in Europe: managing strategic parallel trade legal challenges, author of the stock management scheme
 - Lead legal support to the production and quality activities
- Key achievements
- Built a robust stock management scheme which allowed for a more accurate allocation of the drug at market level and was responsible for considerable company savings
 - Ensured the transition of the business in Latin America from a distribution to a wholly-owned affiliate model
 - Created adequate legal template repositories to further empower affiliates to contract
 - Ensured all the legal support required for a successful transition of the quality activities from the Netherlands to Denmark
- 01/2001 – 11/2004 **Freshfields Bruckhaus Deringer, Paris**
- Supporting acquisitions of groups of companies in various jurisdictions
 - Specific expertise in the representations and warranties from the vendor and subsequent arbitration cases
 - Solid expertise in post-acquisition litigation and arbitration
- 1997 – 2001 **Various trainings at leading law firms**
- Summer internships at Stikeman, Elliott in Montreal, Canada
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Education and on-going professional development

- 2014 Graduated from **INSEAD** executive course on Compliance
 (Healthcare Compliance Implementation Leadership Programme)
- 2010 Completed a two year director development leadership program (**DDP**) at Biogen Idec
- 2008 Graduated from the **ECPM degree at Basel University**, Switzerland (2 year education mainly directed at clinical and regulatory professionals to better understand development steps from molecule to market)
- 2001 Qualification as a lawyer (*Avocat à la Cour*) at the Paris Bar
 Distinction: Paris Bar Chairman Award Laureate ("*Lauréate du Bâtonnier*")
- 1999 – 2000 Graduation from Faculty of Law (University of Lyon III, France), Master of Law in Business and Tax Law ("*DESS droit des Affaires et fiscalité /DJCE*")
 Distinction: Year 2000 Valedictorian ("*Major*")
 Essay presented on cross-border mergers ("*Plaidoyer pour la fusion transnationale*")

1999 – 2000	Advanced Certificate in Company Law with the Faculty of Law - (University of Montpellier I) Distinction: Year 2000 Valedictorian (“Major”) and Laureate of the “Charles Raynaud Award” allocated by the French Association of In-House Lawyers (<i>Association Française des Juristes d’Entreprise-AFJE</i>)
	Diploma in Common Law (English Law) from the Comparative Law Institute Edouard Lambert (University of Lyon III) With honours (Summa Cum Laude) (“ <i>Mention Très Bien, Major</i> ”) Essay presented on Canadian Bankruptcy Procedures in a comparative law approach (“ <i>La faillite en droit canadien</i> ”)
1995 – 1999	Bachelor of Law in Business Law (Maîtrise de Droit des Affaires) With honours (Summa Cum Laude) (“ <i>Mention Très Bien, Major</i> ”)
1995	High School Graduation (<i>Baccalauréat</i>) in Economics, with honors (Summa Cum Laude) (“ <i>Mention Très Bien</i> ”)

IT skills

MS Office (Word, Excel, Powerpoint)

Languages

English	Fluent
French	Mother tongue
German	Good level (Goethe Institut Zertifikat B2 Sehr Gut)
Spanish	Conversational
Russian	basic knowledge

Memberships

Has been the Legal department representative of the Diversity and Inclusion Committee and an active organiser of the Women Innovation Network events at Biogen Idec
Member of CT Legal (Clinical Trial Legal)
Supporting Giving Women activities

Publications, public speaking at conferences, teaching & recognitions

2016	Speaker at CT Legal Conference “Seismic Shifts in EU Data Privacy, understanding impact of the Schrems decision in the conduct of international clinical trials”
2015	Speaker at CT Legal Conference “Mastering compliance risks: key to a successful R&D strategy”
2014	Speaker at the International Pharma Compliance Congress with respect to the compliance challenges in the R&D sponsor related activities
2010 – 2013	Regular speaker within the specialized Clinical Trial Legal forum CT Legal on key R&D issues such as secondary research, contracting with CRO, compliance challenges in the R&D area etc
2009	Winner of the Biogen Idec Leadership Award
2008	Speaker at the C5 Conference on the subject of transparency in the conduct of clinical trials

- 2007 Speaker at the C5 Conference Pharmaceutical Patent Lifecycles on the subject of parallel trade in the pharmaceutical sector “Rising to the challenge of Parallel Trade”
- 2006 Speaker at the VIB Conference on the subject of Parallel Trade
- 2004 Publication in the business daily newspaper “Les Echos”: the impact of French foreign investment regulations on the merger project between Novartis and Aventis (“Comment l’offre de Novartis a été freinée”), Les Echos, 27th April 2004
- Organization of various seminars for the National Association of the DJCE (ANDJCE), for the French Association of In-House Lawyers (Association Française des Juristes d’Entreprises-AFJE) and teaching business law at the Faculty of law of Montpellier and at the Paris Bar School
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Personal facts

Address	Säntisstrasse 93, 8820 Wädenswil
Birth date	07 March 1977
Nationalities	Swiss, Canadian & French
Hobbies	Traveling, cooking, hiking in the mountains, swimming, charity activities within the association Giving Women or the School Parents Committee “Kids for Kids”