

François LAWNY

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From 09/2005 to now **Expert Consultant in industrial biotechnology , Geneva, Switzerland** (Triskel SA from 12/2006).
- Assistance to concept design for a plasma fractionation facility.
- Assistance to concept design for the GMP facilities in Italy and in India
- Several due diligence exercises in the field of biotech product assessment, including audit facilities.
- Various missions for biosimilar drug makers (process review, validation review, optimization)
 -For about 6 monoclonal antibodies
 - 5 other proteins (Insulin, FSH, hGH, EPO, G-CSF)
- Process development optimization (2 years savings!) for a monoclonal antibody
- Upgrade of a biotech pilot plan for GMP production.
- Many missions in regulatory field (Scientific Advices, MAA...)
- Many development gap analysis for biotech products.

2001 – 2005 **Laboratoires Serono SA – Facility of Corsier/Vevey - recombinant proteins production**
Downstream processing director –
- Team of 23 people (engineers and operators) of which 6 managers
- Responsible for the large scale GMP production
- Responsible for the budget ,the production cost assessment and the productivity progress
- Responsible for the technological transfer to production of processes from Development or from external companies
- Coordinator of equipment qualification and process validation
- Set up of purification and buffer preparation areas
- Basic design and detailed design of biotech workshop (USP and DSP review of P&ID, automation FDS, facility dimensioning, layout options selection, value engineering, user representative)

1995 – 2001 **Laboratoires Pierre Fabre - CIPF – Centre d’Immunologie Pierre Fabre**
Industrial development director
- Team of 10 people (3 engineers and 7 technicians)
- Process development (upstream and downstream) of recombinant vaccines and monoclonal antibodies
- GMP production of clinical batches (phase I and II)
- Management of outsourcing and technology transfer for phase III batches
- Basic design of a GMP pilot plant: dimensioning, user requirement, layout review, several simulation)

1994 – 1995 **Biolog SA – Start-up in the field of immuno-analysis**
Director of Biology
- Development of a prototype device for automated immuno-analysis

1985 – 1993 **Centre national de transfusion sanguine CNTS – Les Ulis / Yvelines**
Head of growth factor unit (diversification)
- Development and production of growth factors preparations for wound healing
Development project manager
- Purification and viral clearance process development for coagulation factors (factor VIII, factor IX, PPSB, and other blood plasma proteins (albumin, fibronectin, antibodies))
- Development of a monoclonal with anti rhesus activity for pregnant woman
- Technology transfer to production for viral inactivation treatment
- Set up of a pilot plant

1977 – 1984 **Lab. Biotrol SA – Medical biochemistry reagents - Louvres / Seine St Denis**
Immunology director- Development of several relevant reagents

1974 – 1977 **ITS – Institut Technologie des Surfaces Actives - Compiègne / Oise**
Research engineer – Ligands for affinity chromatography and development of enzymatic probes for analytical purpose.

Training and diplomas

1992 **MBA –ICG Paris**
1976 **Post-doctorate at the University of Uppsala-Sweden-** in the field of protein purification
1975 **Thesis in Biochemistry :-** Enzymatic technology
1971 – 1973 **Institut National Supérieur de Chimie Industrielle de Rouen (INSCIR)**
High school of chemistry – diploma of Engineer in Industrial Chemistry

Languages

French **mother-tongue**
English **fluent - working language**
German **academic knowledge**

IT Windows (Word-Excel-PowerPoint) –Microsoft project + several other internal softwares
Miscellaneous Trekking - Fitness – Married- 3 children – Born on May 29th, 1949