



ProductLife

GROUP

Consulting and Outsourcing
for Life Sciences



R&D and regulatory processes

Business process outsourcing

Electronic documents
and data systems

R&D governance
and R&D IS optimization

**PRO
DUCT
LIFE-
GROUP
.COM**

“Commitment to results
is our motto.
Long term relationship
is our claim.”

HEALTH PRODUCT : A HUGE SET OF INFORMATION

Heterogeneous information

- external structured or unstructured information
- structured computed data
- unstructured reports
- unstructured data assessment



- For health professionals as well as for individual patients a health product is not only a compound/device but a global set of information from all sources, scientific, regulatory as well as public, legal and marketing.

**PRE-CLINICAL
& CLINICAL**

**PRO ACTIVE SAFETY
& INDUSTRIAL RISK MANAGEMENT**

**PRODUCT INFORMATION
& LABELING**

**PORTFOLIO LIFECYCLE
MANAGEMENT**

SUBMISSIONS

AUTHORITIES INFORMATION

DATA MANAGEMENT

SEARCHES IN BIBLIO BASES

DISCOVERY

PATENTS

MANUFACTURING

QUALITY (CMC)

WHO WE ARE

We are a consultancy and process outsourcing company, dedicated to the Life Sciences Industry and particularly to pharmaceutical companies in Europe. Since 1993, our focus has been on electronic data and document management for R&D, and Safety and Regulatory issues. We provide expertise and resources to help our clients continuously adapt their systems, business processes and resources to new regulations and evolving technology.

Our client services

Thanks to our consultants and experts, we cover a wide range of information, data and document management issues.

We ensure and streamline several global business processes, e.g. from authoring, submitting and exchanging with Authorities, to industrial and safety risk management, as well as data and knowledge management throughout the product value chain.

We help our clients choosing and implementing systems in their currently installed IT architecture and processes.

We help them to comply with their own internal requirements.

Our perspective is unique: to integrate new processes into our customer strategies and support their core business focus.

A unique value proposition

Our clients expect a unique and global contractor who proposes all the vital technical, scientific, regulatory and regional expertise and resources.

- **Improving information management processes and systems**

Our highly experienced and specialized consultants contribute to your decision making process. They work closely with you in your diagnostic, vision, selection and change management requirements, independently from any software vendor, developer or integrator.

- **Outsourcing operational processes**

Some operational processes, integrating large data sets, documents or information processing, deserve to be outsourced to our qualified and skilled teams. This type of mission is carried out according to SLAs (Service Level Agreement) with costs, volumes and time commitments.

Working with Product Life

“As regulatory expectations, quality commitments and portfolio complexities are increasing, Life Sciences companies are becoming information management companies as much as manufacturing and marketing companies. The Industry needs to streamline information and promote standards and dematerialization.”

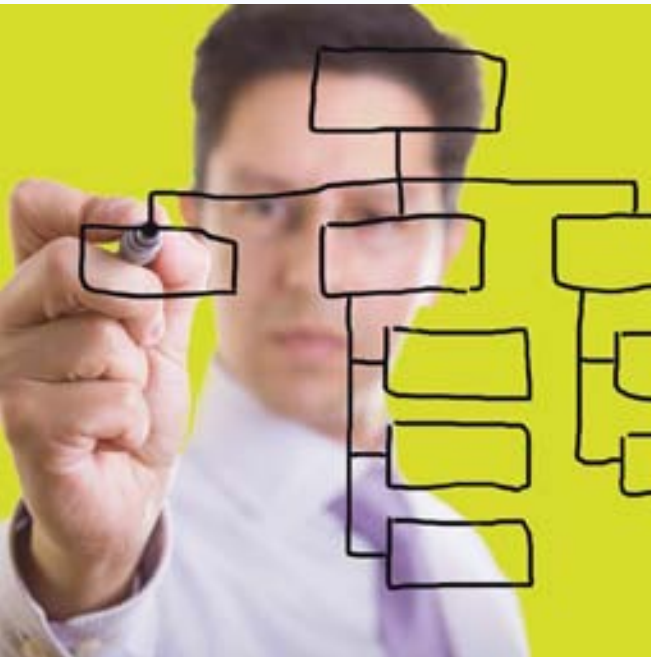
Erick Gaussens (Scientific Head)



FIELDS OF EXPERTISE

R&D and Regulatory process

- We analyze the current processes and propose adaptation in line with your strategy and regulatory/quality requirements : this applies to any area in R&D, in particular Regulatory, Clinical, Non-clinical, Pharmaceutical development (CMC, Manufacturing), Safety and Quality.
- We model pragmatic target processes in relation to supporting IT systems and update or create related procedures.
- We implement change management programs, including communication support and user training.



Business process outsourcing

- We build, provide and manage right-on-target teams.
- Some of the business processes targeted :
 - Document management and preparation of regulatory documents for electronic submissions (eCTD Dossiers writing, formatting and publishing) in national or international regulatory contexts
 - Document and data bases management, legacy data migration and archive management
 - Medical and pharmaceutical writing, bibliographical searches
 - Templates design and authoring tools customization
 - Contracts with third party management
 - Scanning, OCR, indexation

Electronic Document and data systems

- We help our clients to choose and successfully implement key systems, from the scoping phase to user training. These systems mainly are :
 - Electronic document management systems
 - Electronic submission systems
 - Regulatory tracking
 - Portfolio management
 - Risk management
- We help project managers and project sponsors to run meetings (steering committees, meetings with users, meetings with IT...) and take charge of writing project business deliverables: user requirements, validation plans, user guides... We also help project teams to check and validate IT deliverables (documents, software).

R&D Governance and R&D IS optimization

- Information System mapping
- Information Strategic Plan and Validation Strategy
- IT global architecture in line with industry requirements



OUR BUSINESS ENVIRONMENT

A European scope

We address various sectors in the Life Sciences Industry and particularly in the European pharmaceutical sector. We also address medical devices, veterinary and cosmetology sectors.

We work with the largest global companies in the Life Sciences Industry and also provide services to mid-sized and biotech companies.

Our teams of professionals

Our staff of professionals is fully involved in the Life Sciences field. Most of them have an expertise in both business and IT domains. They are ideally balanced in terms of seniority. All of them have technical, regulatory, scientific and pharmaceutical backgrounds or regional expertise. Their professional skills, knowledge and know-how are constantly refueled by the various missions they accomplish.

Some of our clients

Baxter, Bioalliance, Cephalon, Chugai-pharma, Galderma, GSK-Bio, Guerbet, Ipsen, Janssen Cilag, Johnson & Johnson, Laboratoires Servier, Laboratoires Théa, LFB, Stallergènes, Macopharma, Merck Serono, Novartis France, Pierre Fabre, Sanofi-Aventis, Sanofi-Pasteur, SPMSD, Theramex, UCB.

Special connections

Our staff has been building long-term and strong relationships with various Authorities (Afssaps, EMEA) as well as with global and local business and academic representatives and associations (membership in the DIA, DIJ editorial board, Eudipharm lecturer, membership in HL7, co-organizing seminars with Université Paris Descartes, authoring different publications, academic contributions, etc). This invaluable network allows us to permanently improve our competencies and be privy to our client's insights. This is highlighted by our monthly Breakfast Meetings organized for 6 years in Paris, and now also in Brussels, around burning industrial issues.



ProductLife

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2009 : OPENING OF A SWITZERLAND OFFICE

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PLANNED FOR 2009-2010 : BELGIUM, UK AND SPAIN OFFICES

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