



NetContact GmbH

PharmaConsulting & Technical Office

"We care about your Healthcare Business"

NetContact is an Austrian based life science advisory company founded in 2001.

NetContact Advisory provision of services is addressed to international and national pharmaceutical companies as well as health institutions.

www.netcontact-oeg.at

NetContact's Unique Selling Point lies in **operative and strategic medicinal and economical** customer consulting. NetContact's Senior Experts bring along long experience in leading positions in the pharmaceutical industry and as consultants.

Besides the operation as a consultancy NetContact has developed an innovative Life Cycle Management **database named PARACEL-SUS** in-house.

Imprint:

NetContact Unternehmensberatungs- und Handels-GmbH Pharma-consulting

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COMPANY PROFIL AND PHILOSOPHY

NetContact's mission statement:

"We care about your Healthcare Business"

NetContact provision of services addresses companies in the international and Austrian pharmaceutical industry as well as authorities and health organizations.

NetContact is registered in the list of the Pharmaconsulting Companies of PHARMIG and IGEPHA.

MARKETS AND COMPETITION

The classic pharmaceutical markets show a stable growth globally. Though the economic and political basic conditions change holding following main characteristics:

- You can observe a movement of the growth away from the advanced markets e.g. USA and EU towards the upcoming new markets such as China and India, and also from „primary class“ medicinal products towards biotechnological manufactured products and specialised medicinal products.
- Generics will further increase their acceptance and importance.
- M&A as well as collaborations between big players, biotech and universities will further improve their influence.
- Increasing complex requirements of international and national health authorities, e.g. the eCTD format, paediatric clinical development programs, risk management, pharmaceutical quality measurements call for broad knowledge.
- National guidelines have to be followed exactly by manufacturers and distributors of medicinal products, e.g. Arzneimittelbetriebsordnung (AMBO).
- Efficient product databases and life cycle management are pre-conditions for pharmaceutical safety issues and cross-national pharmacovigilance systems.
- Total Quality Management (TQM) and standardizing of all processes will also gain in importance as keys to economic success.





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TEAM

NetContact was founded by **Eva-Maria Schwarz and Josef Schwarz in 2001** in Grossriedenthal near Vienna. Both managing partners of NetContact spent the larger part of their professional life in diverse senior and leading positions in the pharmaceutical industry and as consultants.

Josef Schwarz has a **concession for manufacturing and wholesales with medicinal products and poisons according to the Austrian law.**

Dipl. Ing. Josef Schwarz (Managing Partner)

Area of responsibility and expertise:

Regulatory affairs, quality operations, total quality management incl. GCP, GLP and GMP, project management for herbal medicinal products and orphan drugs. Further Medical affairs including clinical trial management, clinical development and monitoring, pharmaceutical quality assurance, audits and medical information services, pharmacovigilance, and training courses, workshops, presentations. The special competence of Josef is data base programming in Visual Studio, Client/Server Technology and Programming, network technology, workflow management and internet technology.

Background:

Josef has a university degree in chemistry from the Technical University of Vienna. He was research assistant at the Austrian Institute for Timber, Pulp and Paper Research and afterwards spent twenty years from 1981 to 2001 in different leading positions in sales, regulatory affairs and clinical development in the international pharmaceutical industry in Austria. Josef was also responsible for the development of an IT supported workflow management system. From 1999 to 2001 Josef was business development director at AstraZeneca Austria.

Eva Maria Schwarz (Managing Partner)

Area of responsibility and expertise:

Regulatory affairs, pricing and reimbursement for medicinal products, labelling and change control, public relations.

Background:

Eva studied pharmacy at the University of Vienna and is also trained as a dental assistant. Evas' professional carriere ranges from executive secretary at the Institute for Ecological Hunting in Lower Austria, where she was lecturer, to Regulatory Affairs Officer at Astra and later AstraZeneca in Vienna.





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PRODUCTS AND SERVICES

In times, where complexity of development and time to market of the product are especially challenging, reliable and experienced partners are essential for the economic progress.

Products and services of NetContact cover all areas of the life science industry. For a more detailed listing of all the products and services please visit our homepage, www.netcontact-oeg.at.

NetContact offers following **products and services**:

Regulatory Affairs

Regulatory affairs services cover preparation, compilation, coordination and monitoring of national and European drug applications and marketing authorizations (CTD), product life cycle management, lobbying the health authorities and the most important decision makers in the health sector (EMA, AGES). Besides this we would be glad to give you advice concerning new guidelines for e.g. paediatric clinical development, etc. and carry out trainings in all regulatory issues accordingly.

NetContact Senior Experts prepare advisory opinions for the health authorities (AGES).

Pricing

The activities in this field cover, amongst others, project management for the development of a pricing strategy for single medicinal drugs or a whole portfolio, health economics, price negotiations on behalf of the client with the pricing commission of the Austrian Feder-

al Ministry and the Austrian Board of the Austrian Health insurance agencies, as well as price catalogue management.

Business Development

NetContact executes analyses of existing product portfolios as well as of technology platforms (in-licensing candidates). We act as a connection for potential business partners for academic and industrial collaborations. We prepare for due-diligence processes within the scope of planned collaborations, licensing agreements, financing rounds, etc.

Marketing

We offer strategic marketing, status quo analyses and feasibility studies and compile proposals for solutions for the products in the complete product life cycle. Furthermore we have specialized in operational marketing, by highlighting, how you can turn the famous „4 P“ marketing mix screws (product, price, promotion, placement). In addition, NetContact offers pre-launch activities incl. Implementation plans, communication strategy, key account management at scientific opinion leaders, compilation of product monographs, etc.

Market Research

NetContact has specialized in secondary market research of life science questions.

NetContact analyses your R&D programs and product pipelines, identifies new Therapeutic areas, or distribution channels for already marketed medicinal products (portfolio check). NetContact also compiles business intelligence reports, for e.g. demonstration of the activities of the competitors for the management concisely.


Pharmacovigilance

The requirements for drug safety on the part of the legislator are accurate. The execution and implementation of the requirements are the subject of permanent inspection. NetContact supports its clients in all issues on drug safety, covering the adaption of Pharmacovigilance SOPs and agreements and the reporting to authorities, specialists, etc. according to the client's specifications besides compilation of an individual pharmacovigilance system.

Quality and Processes

NetContact's experts are certified quality managers and auditors, who execute status analyses of all processes and structures of the





clients e.g. in the area of stock management, production, logistics, etc. to create the whole company output more efficiently and effectively. A focus of our services is directed to the configuration of processes according to the "Arzneimittelbetriebsordnung 2009" (AMBO) and the pharmacovigilance regulation. This comprises operational and organizational structures, necessary documentation such as quality assurance handbook, standard operating procedures (SOPs) and audits to the point of establishment of a complete quality management system according to ISO 9001:2000.

Clinical Development and Post Marketing Surveillance (PMS)

NetContact's „package for clinical development“ comprises clinical development, medical affairs and post marketing surveillance for single products or projects, as well as for the whole portfolio including traditional human medicinal products (incl. homoeopathics), vaccines, herbal medicinal products and orphan drugs.

Medical Writing

The services in the field of medical writing are complex; please contact our homepage for further details.

Project Management

NetContact is specialised in the common project management of complex questions and projects in the pharmaceutical industry. On behalf of the clients, NetContact identifies and assesses providers of services, developer and manufacturer for the pharmaceutical industry. Furthermore, NetContact contributes to the planning and implementation of outsourced projects.

PARACELSUS Database

PARACELSUS is the leading product of NetContact, which was already developed about 20 years ago in-house. PARACELSUS is a user friendly data base for the administration of complex product life cycle and project management tasks. PARACELSUS is based on SQL data and any frontend such as MS ACCESS, and is single user or network-compatible.

PARACELSUS is available for the clients by acquisition of a license, after which no further access license fees are necessary. NetContact supports you in the implementation of the data base and gives training directly at the clients.

Technical Office

NetContact offers to the clients several services in the field of the concession for a technical office ("Technical Office for Technical Chemistry"). This includes technical project management for process and structure analyses for new labs or manufacturers for the pharmaceutical industry.

Presentations and Workshops

NetContact's Senior Consultants provide support for the compilation of presentations for scientific meetings and congresses, summary of study results for publications in scientific journals (English and German), trainings for the representatives and preparation of training material for staff in the area of life science, conception and implementation of "train the trainer" programs, etc..





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Dipl.Ing. Josef Schwarz

Responsibility:
Regulatory Affairs, Quality Operations and Management, Medical Affairs and Medical Information Services

Over 25 years of industry experience in leading positions and consultant for pharmaceutical industry and health authorities. Josef holds a master's degree in chemistry.



Eva Maria Schwarz

Responsibility:
Regulatory Affairs and Product Life Cycle Management

20 years industry experience in the middle-management and consultant for pharmaceutical industry and health authorities. Eva was trained in pharmacy.



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PRODUCTS AND SERVICES

The life science products and services of NetContact are in the field of:

- Regulatory affairs
- Pricing and reimbursement
- Product development
- Business development
- Marketing and market research
- Pharmacovigilance
- Quality and process management
- Clinical development and medical writing
- International project management
- PARACELSUS life cycle management data base

NetContact Experts further stand by in a **“one-stop-shop”** principal in all operative and strategic projects, e.g. also in **„management by time”, due diligence processes** and in the **search for external manufacturers** and **collaboration partners**.

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