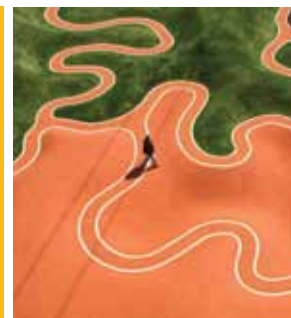


# IDRAC<sup>®</sup>

## DATABASE CONSULTANT NETWORK



The Scientific business of Thomson Reuters works with an international network of consultants, each with in-depth local expertise. As a result, each module in the IDRAC database contains Regulatory Summaries focused specifically on the module's region, written by experts from the region.

Our approved consultants can provide individual services, supplementary to an IDRAC subscription.

We are proud of our worldwide consultant network which includes the following, by country.

**Please click on the countries below to find details of each country consultant.**

### IDRAC PRODUCT OFFERINGS

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Argentina	Czech Republic	Italy	Slovakia
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Baltic countries	France	Malta	Spain
Belgium	Germany	Mercosur	Sweden
Brazil	Greece	Mexico	Switzerland
Bulgaria	Hong Kong	Netherlands	Taiwan
Canada	Hungary	Norway	Thailand
Chile	Iceland	Poland	Turkey
China	India	Portugal	Ukraine
Colombia	International	Romania	United Kingdom
Croatia	Ireland	Russia	United States
Cyprus	Israel	Singapore	Vietnam



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## IDRAC DATABASE: CONSULTANTS - ARGENTINA, CHILE, COLOMBIA

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SVS is the leading validation and compliance consulting company in Spain, Argentina, Italy, China and Algeria.

Our mission is to provide high-value validation and compliance services to our customers.

Our goal is to offer to our customers a complete and integrated range of validation and compliance services through a flexible, practical, objective, cost-minimizing and investment-optimising approach.

#### SERVICES PROVIDED IN THE FOLLOWING AREAS:

- Regulatory Affairs Consulting Services (Implementation of national and international regulations related to registration, review of dossiers and assessment of their level of compliance with current regulations).
- Strategic partners: (MA, marketing licenses, market studies, assistance to foreign companies to enter the local market).
- Compliance Auditing Services: (Integral diagnosis and pre-inspection / pre-approval audit, Audit of compliance with the CFR 21 part 11 regulation regarding computerized systems, Audit of suppliers, Quality Assurance Systems audit and ISO 9000 audit).
- Quality System Consulting Services (Consultancy and Inspection Preparations, Quality Assurance)
- Validation Services: (based on a quality system and the use of our own high quality).
- IT System Lifecycle Management: introducing Good Practices for information Systems.
- Training solutions (in-company training).

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## IDRAC DATABASE: CONSULTANTS - ASEAN, HONG KONG, MALAYSIA, SINGAPORE, TAIWAN

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#### RIGHT FROM THE START, RIGHT TO THE END

Are you looking for reliable regulatory consulting that works diligently for you? At Omnicare Clinical Research, our Regulatory Affairs professionals are dedicated to ensuring the successful and timely submission of your application. We work closely with you, from project initiation to completion, to determine your specific business needs and to meet your timelines. Our experts can provide the strategic regulatory guidance to:

- Expedite the compilation and submission of your application
- Produce a submission acceptable to local and/or global regulatory authorities
- Facilitate regulatory review to achieve faster study initiation or product approval

#### THE ROAD TO SUCCESS

Success speaks for itself. Omnicare Clinical Research has contributed to the successful approval of numerous regional and global investigational and marketing applications without receiving any notifications of clinical hold/objection or refusals to file. To date, these submissions include 58 NDAs/BLAs, 24 MAAs (including CTDs), 124 national filings (including CTDs), 7 Orphan Drug applications and many INDs, CTAs, and CTNs. Our 100% global success rate demonstrates that we have the ability to manage submissions worldwide, the experience to meet timelines and the drive to produce results.

#### COMMITMENT TO QUALITY

Selecting the right consultant is critical to ensuring the quality and success of your project. At Omnicare Clinical Research, we understand that a properly-prepared submission is critical to the approval process of your application. We meticulously review all submissions for completeness and assemble each submission according to regulatory requirements. Our regulatory track record demonstrates our commitment to quality. When you trust your project to our regulatory experts, you gain the extensive experience and unparalleled success that is the hallmark of Omnicare Clinical Research.

#### READY TO DELIVER

Experience ensures readiness for any challenge. Omnicare Clinical Research has the global regulatory expertise and the knowledge of applicable regulations to oversee submissions to U.S., EU, Japan, Asia-Pacific and Canadian regulatory authorities. Examples of our services include:

- Regional and global product development and registration strategy
- Compliance audits for good clinical/laboratory/manufacturing practices (GxPs)
- Drug import/export
- Implementation of internal change control systems
- Report preparation/publishing/submission
- Clinical trial authorizations (e.g., IND, CTA)
- Marketing authorization dossiers (e.g., NDA, MAA, dossiers in CTD format)
- Creating prescribing information
- Assessing advertising and promotional materials
- Regulatory authority liaison
- Regulatory intelligence/due diligence
- Post submission support (e.g., annual reports, amendments, variations)
- Training seminars

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## IDRAC DATABASE: CONSULTANTS - AUSTRALIA

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Symbiotic research is a joint venture company of three partners providing contract research and business development of biotechnology, pharmaceutical, devices and diagnostic product. This is a unique and comprehensive combination set of skills to bring a product through preclinical and clinical trials to market in a pragmatic and business environment with understanding of the international regulatory scene.

The company was formed in 1997 from three companies with longstanding (over 8 years each) and extensive, recognised, experience in the health, life science and biotech industries in Australia and the region.

#### A FULL RANGE OF SUPPORT INCLUDES:

- Project Management
- Regulatory affairs including EU, FDA, CSA, TGA
- Manufacturing feasibility and sourcing, conformation to GMP and GLP.
- Preclinical studies including product efficacy trials and toxicology using animal and in vitro methods conforming to ISO 9001, and GLP
- Clinical trial management to GCP standards
- Business Development and commercialisation
- Fundraising and strategic partnerships

We provide thorough understanding of the Australian regulatory scene in the international market for efficient and cost effective product development; commitment of a project manager who will ensure continuity of each step of the assignment; and potential cost benefits due to:

- Favourable exchange rates with the Australian dollar
- "One stop shop" means reduced duplication and management time
- Ready access to local project managers for discussion

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## IDRAC DATABASE: CONSULTANTS - AUSTRIA

### ARAC (At Regulatory Affairs Consulting GMBH)

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### Dr. Ingrid Huber-Strubl

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ARAC (At Regulatory Affairs Consulting GMBH) is a team of experts specializing in the marketing authorization of medicinal products, eCTD, pricing and reimbursement strategies, and pharmacovigilance. The company is based in Vienna, near the centre of the city.

#### THE COMPANY OFFERS THE FOLLOWING SERVICES:

- Marketing authorization: Marketing authorization of medicinal products in the EU
- eCTD: Preparation/reformatting of the registration dossier
- Pricing strategies: Evaluation of pricing strategies for the Austrian market
- Reimbursement applications: Inclusion in the Code of Reimbursement
- Pharmacovigilance: Taking over of pharmacovigilance activities
- MedDRA: MedDRA coding for pharmacovigilance and PSURs

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## IDRAC DATABASE: CONSULTANTS - BALTIC COUNTRIES (ESTONIA - LATVIA - LITHUANIA)

### DOKUMEDS

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DOKUMEDS supports phase II, III and IV clinical trials.

## SERVICES INCLUDE:

- Project Management
- Extensive clinical investigator network
- Selection and set up of study sites
- Effective study monitoring
- Excellent GCP education
- High quality regulatory affairs management
- Development planning
- Trial design
- Bioavailability studies
- Data management and statistical analysis
- Medical writing

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## IDRAC DATABASE: CONSULTANTS - BELGIUM

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SGS Life Science Services, a Business unit of the SGS Group, has 30 years of experience as a global contract service organization providing integrated solutions from preclinical activities to Phase I through IV trials, bio-analytical and QC testing. With more than 1,300 employees and 2,000 clinical trials performed, SGS Life Science Services serves the pharmaceutical, biotechnology and medical device industries.

SGS enables clients to improve efficiency in drug development timelines and decision making.

The SGS Group is the global leader and innovator in inspection, verification, testing and certification services. With more than 50,000 employees, SGS operates a network of more than 1,000 offices and laboratories around the world.

Additional information about SGS is available at [www.sgs.com/CRO](http://www.sgs.com/CRO).

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## IDRAC DATABASE: CONSULTANTS - BRAZIL

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Silvia V. Fridman e Associados was established in 1998 with the main objective of working as a close partner with companies that carry out activities related to products subject to the Sanitary Surveillance System including: Medicinal products; Cosmetic products; Health products and Sanitary products.

Current and past clients include the former Brazilian Pharmaceutical Industry Association (ABIFARMA) currently, the Brazilian Pharmaceutical Industry Federation (FEBRAFARMA), The Brazilian Active Pharmaceutical Ingredient Association (ABIQUIF), The International Drug Registration Assisted by Computer-IDRAC (an international regulatory intelligence database); multinational and national pharma-chemical (APIs) and pharmaceutical laboratories in Brazil, wholesalers and distributors of medicinal products.

Silvia V. Fridman e Associados provides operational, strategic and organizational consulting and supportive services in regulatory affairs and sanitary surveillance and in pharmaceutical marketing support.

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## IDRAC DATABASE: CONSULTANT - BULGARIA

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Dr. Tatyana Benisheva-Dimitrova is Associated Professor on Drug Regulatory Affairs at the Faculty of Public Health at the Medical Academy in Sofia.

A former director of the drug policy department at the Ministry of Health in Bulgaria, she was directly responsible for establishing Bulgarian pharmaceutical legislation in 1995. She continues to shape this legislation thanks to her long tenure as a scientific expert at the Bulgarian Drug Agency and her thorough knowledge of medicinal procedures.

She was granted an EU-CADREAC scholarship and completed an MD in Drug Regulatory Affairs (2004/2005) at Bonn University.

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## IDRAC DATABASE: CONSULTANTS - CANADA

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CanReg Inc. is one of Canada's premium consulting companies offering market access for healthcare technology.

The company provides assistance in drug and device registrations in Canada, including: New Drug Submissions, Investigational New Drug Submissions, DIN Applications and Device Registration.

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## IDRAC DATABASE: CONSULTANTS - CHINA

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### Dr. Xu Ning, EVP, Business Development

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### Yao Zhong, Regulatory Affairs Manager

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Excel is recognized by the pharmaceutical and healthcare industry as the leading Contract Research Organization (CRO) in China. Our staff has extensive experience and a track record of achievements in the various aspects of the industry.

### OUR SERVICE COVERS:

- Product registration: Drug, Medical Device, Health Care Food, Cosmetics
- Consulting: From drug R&D to post-marketing
- Clinical trial: Phase I-IV, Import Registration Trial
- Out-licensing: Drug, Health Food
- Data management
- Biometrics

We are one of the few companies with experience in healthcare product and IND/NDA registration and management of GCP trials in China. We have already worked extensively with the Principal Investigators from many top clinical trial centers. In the past five years we have completed over 50 drug registrations and 60 clinical research projects in different therapeutic categories.

Based on the quality of services provided to our clients to date, we have established a reputation of excellence among many international companies. We maintain extensive contact networks and business relationships with key officials and personnel in the government departments (Ministry of Health, State Food and Drug Administration), industry, hospitals and institutional organizations.

In sum, now we become a leading CRO in China and are committed to providing excellent services to meet the needs of our clients and we have the experience and resources to do so.

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## IDRAC DATABASE: CONSULTANTS - CZECH REPUBLIC

### MiRo

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### Mgr. Romana Rožková

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## IDRAC DATABASE: CONSULTANTS - DENMARK, FINLAND, NORWAY, SWEDEN

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Dr Wennerbeck has been the owner and managing director of Novecon Research AB working as a consultant to the pharmaceutical industry for over 20 years. Before that she worked as Director of Research administration and Regulatory Affairs at Astra Draco in Lund. She has experience in project planning and in working with domestic as well as international marketing authorization dossiers and liaisons with regulatory authorities world-wide. As a consultant in Regulatory Affairs and Clinical Research she has been involved in giving advice on regulatory strategy, documentation requirement and overall plans for studies in humans. Dr Wennerbeck has also worked with submitting dossiers for marketing approval and clinical trial clearance in the Scandinavian countries as well as designing study protocols, case record forms, performing and supervising monitoring work for different type of clinical studies. She has been engaged in in-house training and lecturing on clinical as well as regulatory strategy.

Dr Wennerbeck has published approximately 15 papers in the area of organic chemistry and 12 papers in regulatory affairs area. Dr Wennerbeck is now working from her own company Weteko Publisher AB as a consultant to the pharmaceutical industry.

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## IDRAC DATABASE: CONSULTANTS - EU, UNITED KINGDOM

### Skeffington Consultants Ltd

#### Mrs Veronica Skeffington

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Veronica Skeffington has many years experience of working within the pharmaceutical industry and as a consultant. She has a particular expertise in regulatory legal and guideline requirements for the UK and EU. She is very active in professional Regulatory Affairs organisations, including acting as an examiner for courses for regulatory professionals.

### FOR MEDICAL DEVICES COVERAGE:

#### Deavin Associates

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## IDRAC DATABASE: CONSULTANTS - FRANCE

### A.R.C. Pharma

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Founded in 1981, A.R.C. Pharma is a privately owned Regulatory Affairs Consultancy company (Biofides group) with well established reputation and experience in the pharmaceutical industry. Its team of 14 consultants has an extensive know-how in delivering tailored regulatory services to meet customer's needs as well as in preparing and submitting regulatory technical dossiers and economic dossiers.

A.R.C. Pharma provides a very extended range of high quality regulatory advice and support services including:

- strategic regulatory advice and consulting support
- product registration and advertising strategy
- due diligence of pharmaceutical dossiers and facilities
- writing and compilation of EU CTD dossiers, variations and renewals
- national and European submissions and maintenance of dossiers
- interaction and meeting with agencies and experts
- transparency and pricing dossiers
- readability user testing
- regulatory training and seminars
- regulatory intelligence services and information circulars
- licensing and acquisitions

A.R.C. Pharma acts on behalf of over 200 companies mainly in Europe. The clients of A.R.C. Pharma range from small start-up biotech companies to large multinational pharmaceutical companies.

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## IDRAC DATABASE: CONSULTANTS - GERMANY

### EUDRAC GmbH

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EUDRAC GmbH is an independent European Drug Regulatory Affairs Consultancy established in 2002 and provides a wide range of services for regulatory affairs

and clinical research to the pharmaceutical and medical device industry for the European market.

Regulatory affairs services on European and national regulatory and data requirements, the preparation/organisation of marketing authorisation dossiers in CTD format, conversion of other dossier formats into CTD as required for the European markets, centralised/mutual recognition and national marketing authorisation applications, support for responses to deficiency letters, maintenance of existing marketing authorisations (variation and renewal applications); writing services for documents needed for regulatory submissions (summary of product characteristics, patient information leaflets, labelling, CTD summaries) and translation services.

Clinical Research services include consulting services on European and national regulatory requirements, writing of the required Patient Informed Consent Forms in the respective national language, assistance for CRF and other document translations, insurance, labelling, ethics committee applications, clinical trial applications (IMPDS) for all EU Member States.

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## IDRAC DATABASE: CONSULTANTS - GREECE

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Zeincro Hellas S.A. is a leading Greek – based company which operates as a contract organization to the pharmaceutical industry.

### ZEINCRO HELLAS PROVIDES:

- Consultancy services and co-ordination of pre-clinical research projects
- Design, co-ordination, management, conduct and follow-up of phase I-IV clinical trials
- Data management, biostatistics, expert report, medical writing and pharmacoeconomic services
- Internet-based clinical trials using Hypernet with high level of encryption
- Regulatory affairs services including pharmacovigilance and national/international submissions
- Training services and organization of tailor made courses, meetings and seminars
- Business development, licensing-in and licensing-out products and marketing services

Zeincro Hellas clients' are local and multinational pharmaceutical companies, medical centers, health funds, doctor's associations, collaborating CROs etc.

For further details, please visit our site:

**www.zeincro.com**

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## IDRAC DATABASE: CONSULTANTS - HUNGARY

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Baker & McKenzie the world's first global law firm, has over 60 offices in more than 30 countries. With the opening of the Budapest Office in 1987, Baker & McKenzie became the first Western law firm to establish an office in Central and Eastern Europe. Over the past 19 years, the Budapest Office became one of the largest law firms in Hungary and has developed extensive experience and expertise in several practice areas, including corporate and commercial law, competition law, public procurement law, mergers and acquisitions, project finance and banking, employment law, IT and telecommunications law, intellectual property law, tax law and real estate matters.

Being a member of the Firm's European Pharmaceuticals and Health Care Practice Group, the Budapest Office advises pharmaceutical and health care clients, including a number of multinational pharmaceuticals companies, on a wide range of legal issues in connection with their operations. We advise our clients in connection with the regulatory and licensing aspects of research, manufacturing, distribution and marketing of medicinal products as well as borderline products (e.g. medical devices, cosmetics and foods). We have developed special expertise on clinical trials, pharmaceutical advertising and promotion. We assist our clients in price negotiations with the Government. We also advise our pharmaceutical and health care clients on various intellectual property and tax law related issues. The Pharmaceuticals and Health Care Practice Group of the Budapest Office consists of five lawyers who are actively involved in the above matters.

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## IDRAC DATABASE: CONSULTANTS - INDIA, SOUTH KOREA, THAILAND, VIETNAM

### GLENEAGLES CRC PTE. LTD

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#### Dr Anjali

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Gleneagles CRC PTE Ltd (GCRC) is an Asian clinical research service provider with offices in Singapore, Bangkok, Manila, Beijing, Shanghai and Jakarta. By 4th quarter 2006 GCRC will also have offices in Perth, Australia and Seoul, Korea. It is a wholly owned subsidiary of Gleneagles Hospital (a Parkway Holdings Group of Companies, [www.pgh.com.sg](http://www.pgh.com.sg)).

Gleneagles CRC PTE Ltd provides access to hospitals and patients in India, China, Australia, New Zealand, Singapore, Thailand, Philippines, Malaysia, Vietnam, Indonesia, South Korea, and Hong Kong.

### GLENEAGLES CRC PTE LTD PROVIDES:

- Feasibility Studies
- IRB/EC Submissions
- Clinical Coordinators
- Clinical Monitors
- Clinical Project Management
- Clinical Data Management
- Biostatistics
- Product Registration in Asia
- Regulatory Affairs
- Phase I Studies (BE, BA, PK, PD)

Our regional research network in Asia enables us to assist our clients in both a time- and cost-efficient manner in preparing regulatory submissions to the recruitment of patients. GCRC is able to ensure that all regulatory submissions adhere to the requirements of local regulatory authorities, thus expediting the clinical trial approval process and importation of investigational product for the conduct of the clinical trial.

GCRC has the experience and knowledge in conducting clinical trials across the Asia-Pacific region. We have an added advantage of operating within the local defines of the various Asian countries by having the knowledge of the local healthcare dynamics, cultures and languages to streamline clinical research.

Gleneagles CRC PTE Ltd is the only CRO to have won the Asian CRO of the Year Award (Singapore).

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## IDRAC DATABASE: CONSULTANTS - IRELAND

### Akos, Ltd.

#### Akos Limited

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AKOS Ltd is a well-established private company set up by the owner and CEO Paul Evans in 1986. One of its major focuses is on international Regulatory Affairs, where it offers a full range of services including strategic consultancy and planning, clinical trial authorisation applications, and preparation and management of single- and multi-country submissions for marketing approval. AKOS will undertake complete projects, or perform discrete tasks, according to client needs. Allied to Regulatory Affairs is Regulatory Compliance, offering a range of audit services of facilities, systems, data and reports to GCP and GMP standard. AKOS offers consultancy in drug development and support in planning and executing projects in the earlier stages

of development, from pre-clinical through to proof-of-principle. This includes assistance with all aspects of early clinical research from protocol design through to data entry, statistical analysis and report writing. Akos provides drug safety monitoring and reporting services, as well as post-marketing pharmacovigilance.

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## IDRAC DATABASE: CONSULTANTS - ISRAEL

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Mr. Yaakov Cass has been active in every aspect of pharmacy in Israel for over 30 years. In 1994 he was appointed by the Ministry of Health to the position of regional pharmaceutical officer and sometime adviser to the Minister of Health. He is familiar with almost every aspect of pharmaceutical legislation in Israel and continues to shape future legislation, actively consulting with the uppermost echelons of the Ministry on a regular basis. He is frequently requested by Israeli pharmacists to assist in resolving pharmaceutical issues without the framework of his official position.

Outside the Ministry, Mr. Cass is a prolific lecturer and writer reflected by over 100 publications and presentations. He is an honorary lecturer to the Hebrew University School of pharmacy lecturing on the law of pharmacy in Israel.

He holds a master's degree in clinical pharmacy from the University of Manchester and a fellowship of the Royal Pharmacy Society of Great Britain for distinction in the profession of pharmacy. In 2009 he received an ASHP scholarship to participate in the Boston Universities School of Management Pharmacy Leadership Program.

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## IDRAC DATABASE: CONSULTANTS - ITALY

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EUROPHARMA 2000 is a client-oriented company providing services and consultancies for pharmaceuticals and medical devices. Services range from clinical trials, regulatory affairs and medical writing; consultancy is aimed both to understand the company's needs and to help the company in keeping the right strategic decision for research and development of medicinal products.

The Manager of EUROPHARMA 2000 has a 25-year experience as research and development director of a leading multinational pharmaceutical group. His activity

has been focused on safety evaluation and pharmacology of cardiovascular, analgesic and antifungal drugs; clinical trials in cardiovascular diseases, gynecology, dermatology and rheumatology; worldwide regulatory affairs of medicinal and other healthy products.

The consultancies and service provided by EUROPHARMA 2000 for Regulatory Affairs are the following:

## MARKETING AUTHORIZATION APPLICATIONS (MAA) FOR MEDICINAL PRODUCTS

Submission and post-submission support for:

- National (Italian) Procedure
- Decentralized Procedure.
- Mutual Recognition Procedure

## COMMON TECHNICAL DOCUMENT (CTD)

Regulatory compilation and writing in CTD format of administrative, manufacturing, pre-clinical (Modules 2.4, 2.6 and 4) and clinical (Modules 2.5, 2.7 and 5) data according to the relevant up-dated Directives and Guidelines.

## ELECTRONIC COMMON TECHNICAL DOCUMENT (ECTD)

Compilation and submission of MA applications in electronic CTD format.

## PRICE / REIMBURSEMENT NEGOTIATION WITH AIFA

- Development of price dossier and relative assistance with the Italian Medicines Agency (AIFA).

## REGULATORY WRITING / REVISION OF:

- Patient Information Leaflet compliant to readability user testing guidelines;
- Summary of Product Characteristics and Labelling;
- Translations from English, French, German, Spanish

## VARIATIONS OF MA FOR MEDICINAL PRODUCTS.

- Compilation and submission of Type I Variations.
- Compilation and submission of Type II Variations.

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## IDRAC DATABASE: CONSULTANTS - JAPAN

Please speak to your IDRAC Account Manager for details of local consultants in Japan.

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## IDRAC DATABASE: CONSULTANTS – MÉXICO

**Christel G. Brüggemann S.**

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## INDEPENDENT CONSULTANT

Offers consulting services in Mexican regulatory environment.

## PRODUCTS AND SERVICES

Regulatory Affairs: Regulatory consulting and advice for Mexican Ministry of Health dossier submission, assessing documents.

Review of foreign "Dossier's" and adapting them for Registration in Mexico.

#### DIFFERENT TOPICS

- Elaboration of Quality Manuals
- Good documentation practices and documentation system
- Instructor in GMP's and related topics
- Training of personal in GMP's, GCP's, Monitoring
- Training of plant personal
- Technical Consultant in GMP's
- Qualification of Designs for Pharmaceutical Plants
- Validation

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#### IDRAC DATABASE: CONSULTANTS - NETHERLANDS

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#### IDRAC DATABASE: CONSULTANTS - POLAND

##### **BAKER & MCKENZIE**

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Baker & McKenzie is an international law firm established in 1949. Today, it conducts business in the world's most significant financial and commercial centres, giving us unparalleled geographical coverage and has global network of 66 offices in 36 countries. The Warsaw Office was opened in 1992 and is now the largest office of Baker & McKenzie in Central and Eastern Europe.

The Warsaw Pharmaceutical Practice Group consists of lawyers with relevant legal, regulatory and industry experience, dedicated to providing advice on a wide range of legal issues to pharmaceutical companies of all sizes and who have well established contact lines with national approval authorities.

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#### IDRAC DATABASE: CONSULTANTS - PORTUGAL

##### **PHARMAffairs, Pharmaceutical Consulting - Consultadoria, Lda.**

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##### **Ângela Rocha / Ana Gaspar**

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Pharmaffairs is a Regulatory Consulting Company with services focused on the Pharmaceutical Industry. Our team is specialized in Scientific and Regulatory Affairs and has a broad experience in the Medicinal and Healthcare Product sector.

Pharmaffairs provides Scientific and Regulatory Consultancy Services that match the specific needs of each Client.

Our areas of expertise include Human medicines, Veterinary medicines, Cosmetics, Medical Devices, Nutritional products and others.

Our main regulatory services include dossier preparations (all modules in CTD format) and submission through national, mutual recognition and decentralized procedures, Marketing Authorization maintenance activities (e.g.: Type I and II variations, labeling preparation and analysis, renewals, expert reports), Pharmacovigilance activities, Pricing and Reimbursement and submission of Clinical Trials Applications to the Competent Authority and Ethics Committee. Pharmaffairs also provides high quality technical translations and regulatory training.

Our Project Team offers high quality regulatory solutions, confidentiality and flexibility, with a rigorous fulfillment of timelines.

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#### IDRAC DATABASE: CONSULTANTS - ROMANIA

##### **Lucian Bondoc**

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Salans is an international law firm conducting business with 20 offices in 16 countries, including the world's most significant financial and commercial centers. Salans' Bucharest Office is one of the largest international law firm presences in Romania, its approximately 40 lawyers covering all areas of commercial and civil law.

With over 8 years of experience in dealing with legal life sciences matters, including corporate and competition laws-related, Lucian Bondoc leads Salans' Bucharest' life sciences team. Lucian Bondoc has assisted on a wide range of legal issues to pharmaceutical companies and health companies, including with respect to mergers, tenders, licenses and authorizations, competition law investigations, pricing, advertising, warehousing, clinical trials, hospitality, sponsorship, internal compliance policies, data protection, legal changes, etc.

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## IDRAC DATABASE: CONSULTANTS – RUSSIAN FEDERATION

### ALMEDIS

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### Dr. Maria Nassonova

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ALMEDIS is a contract research and consultancy organization with operations all over Russia.

### ALMEDIS PROVIDES:

- Comprehensive support in international clinical trials management and their execution
- Trial design and medical writing, project management and monitoring, data management and biostatistics for local clinical trials
- Regulatory affairs including review and preparation of all documentation in accordance with local requirements and submission
- Consultancy in medical marketing , scientific medical support in promotion & advertising of pharmaceutical products
- Training for company personnel (Regulatory Affairs and Pharmacovigilance specialists, Clinical Research Associates, Medical Representatives etc).

We provide the tailored solutions to meet the requirements of each client and to turn our comprehensive knowledge and experience into our clients' competitive advantage.

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## IDRAC DATABASE: CONSULTANTS - SLOVAKIA

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We are one of the few Slovak law firms specializing in the field of Medical Law, Pharmaceutical Law and Commercial Law. We provide comprehensive legal services and consultancy to our clients (local and foreign) which are – among the others - the pharmaceutical companies and producers of medicinal products and medical devices. Apart from a legal help in the area of commercial and contract law, we also advise our clients how to cope with administrative and regulatory procedures particularly as regards of manipulation with medicinal products and medical devices, their testing, control of their quality, efficiency and safety, their registration and introduction to market. We have good contacts with the relevant state authorities involved in the process of introduction medicinal products and medical devices to the market,

so that we are able to help our clients effectively in communication with them.

Our priority is the successful resolution of our client's problems, no matter how complex they may seem to those concerned. For this reason we cooperate with the highest quality external consultants.

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## IDRAC DATABASE: CONSULTANTS - SLOVENIA, CROATIA

### Medi.Si Consulting-Svetovanje

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Medi.Si Consulting is a company specialised in translation of medicinal documents and in drug regulation in Slovenia, Croatia, Serbia and Bosnia and Herzegovina.

Apart from the regulatory and legal advice, we offer the translation of texts with medicinal content from/to English, French and Italian to/from Slovenian, Croatian, Serbian and Bosniac language.

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## IDRAC DATABASE: CONSULTANTS - SOUTH AFRICA

### J & B Pharmaceutical Consultants

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### Joy van Oudtshoorn – Eckard

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J & B Pharmaceutical Consultants specialise in human and veterinary pharmaceutical matters, such as:

- Scientific support for patent matters
- Pharmaceutical product development and production trouble shooting
- Bioavailability studies and clinical trials, advice, placement, management and monitoring
- Regulatory Affairs and related training.

The CEO is Prof Bosch van Oudtshoorn. He studied pharmacy and completed post-graduate studies at the University of Potchefstroom. He studied for his doctorate at the Universities in Zurich and Leiden and was appointed as Professor and head of the Department of Pharmacy at the University of Potchefstroom in 1967.

He was the Executive director of Research and Development of South African Druggists, for many years and is the author and co-author of more than 100 scientific publications and two text books, Medicinal Plants of South Africa and Poisonous Plants of South Africa. He is the holder of several international patents in the field of medicine and member of various statutory and professional bodies.

Joy van Oudtshoorn-Eckard is Executive Director, Scientific and Medical Affairs. She is a pharmacist with

post-graduate training in industrial pharmacy who has extensive industry and health authority, regulatory and quality control experience in South Africa and Zimbabwe.

She participates in many MCC and Industry workshops and represents the PMA on the Industry Task Group liaison with the Medicines Control Council. As chairman of the Registration and Bioavailability Specialist Group of the Committee for Science and Technology of the PMA for many years, together with other members of her group, met on several occasions with the Pharmaceutical Committee of the Medicines Control Council, to present and participate in scientific discourse regarding various regulatory matters. She has organised a number of workshops and symposia for the industry.

She is the author of the chapter "Registration in South Africa" in "International Pharmaceutical Registration" edited by A Chalmers, designer and author and also responsible for the "registration and control of pharmaceutical products" module of the honours BSc Pharmacy degree of Potchefstroom University.

She is a member of Special interest groups of International Federation of Pharmacists (FIP) and co-author of two of the Herbal Special Interest group publications and serves on the American Association of Pharmaceutical Scientists, (AAPS) Globalization Task Force - an initiative to reach out to pharmaceutical scientists.

She headed the Medical Department of Ciba-Geigy, being responsible for regulatory affairs, clinical research, pharmaceutical product development, medical/marketing liaison, information services, and drug safety for the speciality, generic, self-medication and vision care divisions preceding the consulting activities.

She is an honorary lecturer in pharmaceutics at several Universities. She is also a well known Church Organist.

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#### IDRAC DATABASE: CONSULTANTS - SPAIN

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##### **Helena Torrent**

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ÁGORA FARMACÉUTICA, S.L., is an independent Regulatory Consulting Company, established in Madrid (Spain) since 1995 to cover a wide range of Regulatory Affairs and Consultancy services for the Pharmaceutical and related Healthcare Industries. Our activity is mainly focused on Regulatory Affairs, including the preparation of CTD dossiers for Registration through National, Mutual Recognition or

Decentralized Procedures to obtain Marketing Authorizations of Human, Veterinary, Cosmetic and Food products, as well as Medical Devices or Herbal products.

We advise our clients on the best approach to obtain Marketing Authorization for their products and to maintain them through the preparation of Variations, Renewals, Labelling Readability tests, Expert Reports...). We prepare Pricing and Reimbursement Procedures and offer Pharmacovigilance services.

Our regulatory activities also include the submission of clinical trials, amendments or specific documents either to Ethical Committees or Health Authorities.

We advise on the preparation and submission of Applications for Storage, Importation or Distribution of products to the Spanish Market.

We also have a qualified translators specialized in Health and scientific translations.

Agora acts as liaison between companies located outside Spain and the local Authorities being an important local link aimed to fulfil the needs and understanding of our clients.

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#### IDRAC DATABASE: CONSULTANTS - SWITZERLAND

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Medius is a consulting and service company engaged in regulatory affairs of pharmaceuticals, medical devices and other healthcare products. Founded in 1997 by Urs Rickenbacher, Ph.D., the company located in the Basle area has for mission to provide optimal regulatory support for their national and international clients.

Our services include: full service in relation to submissions of marketing authorization applications of pharmaceuticals, life-cycle management of existing products (variations, revisions, re-labeling), expert reports on pharmaceutical, toxicological and clinical issues, conformity declaration of medical devices, reimbursement applications, and regulatory training programs.

We provide specialized consulting in the following areas: development of new active ingredients, development of variations for existing products, development of generic compounds, review of promotion material according to relevant law, evaluation and classification in the process of conformity declaration of medical devices, evaluation of borderline products (cosmetics, specialized food, complementary medicinal products), liaising with authorities.

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## IDRAC DATABASE: CONSULTANTS - TURKEY

### ZEINCRO MEDİKAL ARAŞTIRMA VE DANIŞMANLIK A.Ş.

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Zeincro Turkey is established in Istanbul as a full-service CRO and consulting office. Our clients include local and multinational pharmaceutical companies, collaborating CROs and medical centers.

#### WE PROVIDE:

- Clinical trial design and monitoring (Phase I – IV)
- Bioequivalence studies, design and monitoring
- Regulatory affairs and regulatory strategy
- Business development, licensing-in and licensing-out products
- Pricing, reimbursement and market access services
- Training services, organization of seminars
- Data management, biostatistics

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## IDRAC DATABASE: CONSULTANTS - UKRAINE

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