

Bringing regulatory affairs solutions to biotechnology, pharmaceutical, and medical device industries.

KEY SKILLS AVAILABLE TO YOU

Client-driven, project-based market research and risk assessment covering –

*Profitability and likelihood of success
Competitor analysis
International partnering opportunities
Joint licensing*

International Regulatory Dossiers –

*Investigational New Drugs
New Drug Applications
Clinical Trials
Marketing Authorization Procedures:
MRP, CP, National
Variations: CMC, Safety, Indication
License renewal applications
Comparative studies of current science
through literature surveys and case studies
Interactions with corporate teams and
competent authorities
Risk assessments*

Product enhancement and development –

*Interfacing with business development, marketing, R&D,
and management
Training of personnel through regulatory affairs semi-
nars, workshops, discussion groups
Assistance in ethical decisions
Guidance concerning US and EU legislation
Dossier preparation
Regulatory submissions*

Product analytical services –

*Customized strategy development
Case-specific regulatory support
GXP compliance*

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Ph.D.

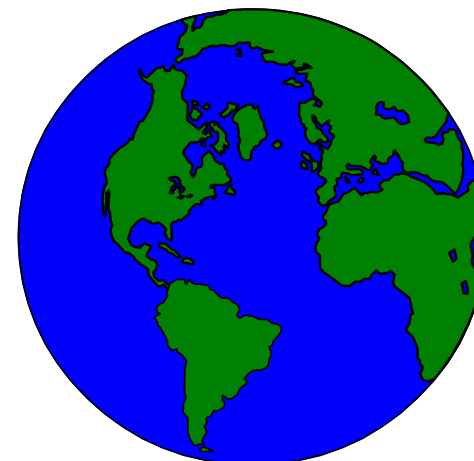


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**UNDINE
SCHACHTSCHABEL
PH.D.**

**CUSTOMIZED ANALYSIS AND
DEVELOPMENT
OF REGULATORY AFFAIRS
SOLUTIONS:**

- ❖ *Biotechnology*
- ❖ *Pharmaceutical Products*
- ❖ *Medical Devices*
- ❖ *USA & Europe*



SCIENCE & REGULATORY STRATEGIES— A PERSPECTIVE ON INTEGRATION

SUMMARY OF EXPERIENCE:

I offer to the regulatory affairs community experience in all phases of pharmaceutical development, and the integration of regulatory strategies into business management practices. My focus is on the analysis, development and improvement of background research that can redirect millions of dollars and years of effort toward more viable development objectives. I can provide guidance and direction for regulatory strategies, submission management, and development of internal and external collaborative efforts.

My work has supported science and regulatory affairs for **Pfizer Ltd., Agouron-Pfizer Inc., Genset Corporation, Abbott Laboratories, University of California, San Diego, Tulane University Medical Center, Markey Cancer Center, Center for Toxicology, and Max-Planck-Institute.**

EDUCATIONAL BASE:

I earned my **Ph.D.** in **Genetics** from the **Max-Planck-Institute** in conjunction with the **University of Cologne**, Germany. My Thesis was “RFLP mapping in *Solanum tuberosum* using random genomic clones”.

I also completed a **Masters in Biology and Chemistry**. Both my graduate and undergraduate studies focused on **Molecular Biology, Genetics, Biochemistry, Microbiology, Parasitology, Organic and Inorganic Chemistry**, from the **University of Hannover**, Germany.

I have presented the following seminars:

- 1) Organic Chemistry: “Aldehydes”;
- 2) Inorganic Chemistry: “Sulfur and compounds”; and 3) Physical Chemistry: “Surface Tension”. I also have presented seminars in Pedagogics and Philosophy, and facilitative classes to high school and college-level freshmen.

I am fully computer literate in platforms and applications that include MS Office (Word, PowerPoint, Excel)/ DOS / Windows; PC, Macintosh; Databases and Statistics.

INCREASE ECONOMIC VALUE OF RESEARCH THROUGH:

Research/Project Validation. Proper assessment of research utilizing databases and in-depth literature surveys on both global and specific related studies will help to achieve optimum focus and direction for development efforts. I could save your organization millions of dollars and years of research time by identifying fact-based directions before actual projects are initiated.

Submission Management to Approval. Deciding on the right strategy for early-to-late stage development brings potentials up to a much higher level of productivity. Submission management also covers routine- and customized procedures for license maintenance, balancing cost against potential benefits and avoidance of expensive duplication.

Compliance measurement and Adjustment.

Compliance is legally binding and crucial to producing operational success. My role is to understand the strategies that have been implemented, recommend and direct adjustments based on US and EU legislation, and develop processes to assure ongoing feedback on matrix team and organizational levels.

In addition, it may be advisable for me to take over certain administrative or operational functions in order to free up senior-level professionals for more critical management functions. These areas might include:

- Allocation of routine procedures
- Submission management
- Customer support
- Technical training and development
- Procedural/protocol development, implementation, and evaluation
- Cost/benefit analysis; alternative cost strategies and prioritization



For information about regulatory
affairs
services available to you please
call:

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