Öztiryaki Pharmaceutical Consultancy and Training Services

The content of scientific documents and materials will be developed, reviewed, revised and written by Dr. Haluk Öztiryaki. He will personally provide the consultancy and training services.

Dr. Öztiryaki has a strong background in one of the large spectrum medical specialties, anaesthesiology and intensive care. Following his specialization in cardiovascular and thoracic fields of anaesthesiology, Dr. Öztiryaki decided to expand his career and experience in pharmaceutical, food supplement and medical device industries as a liaison between medical marketing and clinical/scientific research/regulatory fields.

He has been serving as a medical and regulatory affairs lead in major global and local pharmaceutical companies based on his sound knowledge in various therapeutic fields. Dr. Öztiryaki is providing pharmaceutical services in association with his large experience gained in various functions spanning from medical marketing and sales through clinical research and development.

In one of his latest role, Dr. Öztiryaki served at a multi-national pharmaceutical R&D company in their efforts of pre- and after-launch medical, regulatory and marketing activities in EMA and FDA regions. He also assumed various responsibilities in building the interface of R&D department as a common gateway with marketing and business development functions.

We kindly invite you to visit http://www.oztiryaki.com/oztiryaki_cv.pdf *in order to get further access to the details of Dr. Öztiryaki's professional background and experience.*

I. Medical Research and Clinical Development

1. Study Design (Excluding Statistical Method and Analysis)

- **Planning, design, editing (incl. reviewing and revising) of study concepts, synopses, protocols, case report forms (CRFs), e-CRFs and written informed consents/assents; initiation and management of**
  - ✓ Brand Optimization (BOS) and Life-cycle Management (LCM) studies.
  - ✓ Phase I-IIIa clinical studies (Regulatory studies).
  - ✓ Peri- and post-approval Phase IIIb-IV clinical studies including post-marketing surveillance (PMS), practice-pattern (PP), pattern of care (PoC) studies, investigator initiated trials (IIT, IST), and registries.
  - ✓ Phase V and Pharmacovigilance (PV) studies including post-authorisation safety (PAS) and efficacy (PAE) studies.
  - ✓ Pharmacoepidemiologic studies.
- **Advisory consultancy of clinical development and life-cycle management strategies and projects**
  - ✓ Related to the above project items.
  - ✓ Pharmacoeconomics studies.
- **Investigators meetings**
  - ✓ Strategic planning and programming investigators meetings.

2. Publications and medical writing

- **Strategic publication planning, review, approval, submission and tracking**
  - ✓ Planning and tracking of publications according to regulatory and medical marketing strategies.
  - ✓ Identification of journals, congresses and media for the scientific data to be published and presented in alignment with strategic and tactical purposes.

mob *: +90-533-293 7426* ***e-mail:*** *haluk@oztiryaki.com*

addresse: *Goztepe Mah., Begonya Cad., No: 69 (B57A) 34815 Beykoz / Istanbul - Turkey*

Editing, reviewing, revising and submitting scientific texts

- ✓ Medical writing of abstracts, posters, platform session presentations, journal articles, original research, reviews, commentaries and letters to editor, etc.
- ✓ Production and submission of scientific texts as defined through journal or congress instructions for authors.
- ✓ Proceedings booklets of scientific, regulatory or medical meetings, workshops, etc.

Regulatory Services

1. Regulatory Materials

Developing, updating, reviewing and revising regulatory documents

- ✓ Editing SmPC/CDS and/or patient leaflets according to Turkish legislation (KÜB/KT).
- ✓ Review, revision and follow-up of other regulatory documents including CTDs, e-CTDs, type IA, IB, and II variation files as well as regulatory and market access strategies.

Pharmacovigilance (PV)

- ➢ **Developing, updating, reviewing and revising PV documents**
  - ✓ CIOMS, single-case reporting.
  - ✓ Editing, updating, reviewing and revising PSURs.

III. Medical Information & Communication

1. Medical Information

- ➢ **Developing and indexing product or therapeutic area specific scientific database**
  - ✓ Regular literature search, algorhythmic naming, listing and indexing.
  - ✓ Production of a searchable, indexed full-text, abstract, poster and presentation databases.
  - ✓ Inclusion of scientific and/or business critical documents produced in-house.
  - ✓ 'Endnote' database development.

2. Pharmaceutical Communication

- ➢ **Key opinion leader (KOL), decision maker and healthcare professional (HCP) management**
  - ✓ Definition, segmentation and tracking of a strategic management plan.
  - ✓ Definition of key performance indicators of a successful KOL-HCP management and communication plan.
  - ✓ Inquiry management: Development and filing of standardized scientific letters and management of unsolicited medical and scientific enquiries.
  - ✓ Filtration, assessment and reporting of medical information requests and contacts for drug safety related critical information including serious and non-serious advers events, medication errors (over-dose, posology errors, off-label use, drug abuse, etc), suicide attempt, and pregnancies.
  - ✓ Writing 'dear HCP', 'dear doctor' letters, scientific press release materials.
  - ✓ Advisory consultancy for market withdrawal process.
  - ✓ Development and management of advisory boards and scientific consultant lists including project development.

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IV. Medical Marketing

1. Pre-launch Medical Marketing Readiness

- **Clinical potential of an investigational new drug (IND), investigational new indication or medical device**
  - ✓ Scientific evaluation and reporting of the clinical success potential of an IND, new indication or a new medical device under research and development.
  - ✓ Competitive comparison and benchmarking of scientific and clinical characteristics, unique selling points and differentiation points associated with new and existing pharmaceutical entities in a given therapeutic area.
  - ✓ Strategic scientific communication plan based on regulatory classification and requirements of the IND.
  - ✓ Scientific awareness and launch readiness projects.
  - ✓ Basic medical, therapeutic area, product and PV trainings of the field force.
  - ✓ Development of the field force training materials (content of books, booklets, presentations, exams, etc.).

2. Peri-launch Medical Marketing Activities

- **Production of scientific materials and documents**
  - ✓ Scientific presentations.
  - ✓ Other scientific materials and documents such as press releases, abstract booklets, etc.
  - ✓ Content of product related web-sites and e-mailings incl. measures taken to comply with SPAM acts.

3. Post-launch Medical Marketing Activities

- **Strategic medical support of marketing, sales, market access, clinical and regulatory functions**
  - ✓ Background search, assessment and provision of scientific sources supporting the existing marketing, sales and market access strategies.
  - ✓ Scientific consultancy supporting the development of new strategic marketing plans and tactical decisions.
  - ✓ Situational analysis of commercially related scientific competitive environment.
  - ✓ Field force training and refreshments (basic medical, therapeutic area, product and PV related).
  - ✓ Development of the referenced medical marketing contents, claims and differentiators of the visual detailing aids, summarized and complete presentations, abstract booklets, e-materials, etc.

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V. Pharmaceutical Training

1. Clinical, Scientific and Regulatory

- **Pharmacovigilance and Drug Safety**
- **Pharmacoeconomics**
- **Good Clinical Practices**

2. Medical Marketing and Field Force

- **Basic medical knowledge**
- **Therapeutic areas (neurology, psychiatry, cardiovascular and metabolics, endocrinology, gastrointestinal, urology, anaesthesiology and intensive care, functional food and food supplements, and others)**
- **Product and competitor training**

VI. Compliance and Pharmaceutical Ethics

1. Compliance with Local and Global Regulations / Industrial Codes

- **Consultancy of marketing and clinical projects' compliance with regulations and codes**
- **Revision of projects in order to make them comply with regulations and internal/external codes of conduct**

2. Policies, Standard Operational Procedures (SOPs), Guidances and Checklists

- **Writing, editing, reviewing, revising, updating corporate policies, SOPs, guidances, checklists and other governing legal or regulatory documents in alignment with both local and global regulations and codes as well as corporate mission and vision.**

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