



DHC

Diagnostic Healthcare Consulting

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Our Mission

To analyse & assess

Scientific Projects & Products
in the
Life Science Field

To integrate

Market Needs and Market Trends
into Scientific Projects

To consult

regarding
Product Lines & Extension of Product Lines
Strategic Co-operations
Point-of-Care Tests
Diagnostic BioSensors
Assessment of new innovative diagnostic approaches
Diagnostic Test Developments & Adaptations
Performance & Clinical Utility Studies
Statistical Considerations
Contracting

To optimize

Strategic Fit & Profitability
in
Mergers, Acquisitions
and
Divestitures

To lecture & participate

in
Conferences, Educational Programs
&
Launching / Introduction of new products
Training Activities



Our Services

Product Development

- To perform **analysis** and **overall assessments** for new Life Science opportunities; the field covers both new diagnostic approaches, new diagnostic **analytes** and companion diagnostic, new **methods / technologies** and **analysers** with respect to their potential application in the Life Science field.
- To analyse and assess each project regarding **strengths, weaknesses, opportunities** and **threats** (SWOT-analysis).
- To **work out** those **items** and **specifications (must, wish, nice-to-have specifications)** which are of paramount importance for a successful introduction of a new diagnostic product.
- To work out the **pros** and **cons** of different approaches.
- To **estimate** the necessary work, time and investment in **feasibility, proof-principle** or **clinical studies** which will be necessary to transfer research tests, tools or ideas into products routinely used in the clinical laboratory or in a niche market.
- To **assist** in the development of new products so that they are optimised for the diagnostic routine or research markets.
- To direct and to assist in the optimisation procedure to ensure satisfactory performance characteristics for new analytes, methods and their application.
- To develop **strategies** for the follow-ups and commercialisation of 2nd generation products.

Clinical Studies

- To plan, initiate and perform **clinical studies** for new diagnostic parameters and diagnostic approaches.
- To **advise** as well as to **implement studies** to assess clinical utility (efficacy, clinical specificity, clinical and analytical sensitivity, comparisons and correlation studies) for new diagnostic approaches and diagnostic analytes.
- To make proposals for the choice of the **adequate patient-** and **reference cohort groups**.
- To assist in the **statistical evaluation** and **interpretation** of clinical data

Marketing

- To initiate and manage new relationships or **commercialisation channels**.
- To assist in the **search** for partners and **contracting** with the identified partners. These partners may be in Europe, in the US or in the Far East.
- To assist in the identification and search for **OEM-partners** and for **licensing in & out** activities.
- To take over certain due diligence functions in **mergers, acquisitions** and **divestitures**.

Know-how Transfer

- To participate in internal and external **training** for R&D staff, sales representatives and customers.

Our Approach

- To sign a reciprocal **confidentiality agreement** if there is an interest in exchanging information and in working together
- To **analyse very thoroughly** the tasks, questions, needs and plans of our clients
- To **discuss extensively** with client's key scientists and marketing staff who are involved in the project and **to be part of the team**
- To make a **preliminary assessment** of the project
- To work out a **1st proposal** based on a preliminary **SWOT- analysis** (strengths, weaknesses, opportunities and threats). This SWOT analysis will list under threats all items which are not open at this point in time
- To propose a **plan of action** (PoA) for the project
- If a product is to be **evaluated** or to be **developed** DHC will make proposals for the **concept** and for the necessary **specifications** based on the competitive situation, the market demands, unmet needs and market trends
- DHC will - so the client desires - be **heavily involved** in the **evaluation process** and its **follow-up**

- If clinical studies or if feasibility studies have to be planned, these studies can either be performed internally in the client's company / institute or may be contracted out. In both cases DHC offers its experience to plan, to initiate and to manage these evaluations as fast and efficiently as possible
- The **evaluation data** will be **assessed** and **conclusions drawn**
- Based on a 2nd SWOT analysis proposals will be made with respect to the **value** of the **project** and **how** to **commercialise** it
- DHC will update the client on a regular basis concerning the status of the project. Reports will cover not only the status but also positive and negative issues which arose during the evaluation and during the reporting period; DHC will update its proposal any time a new situation warrants it
- The proposal for "commercialisation of a project" may cover:
 - The development of the project into a **product**
 - **Licensing** out of the project on a non-exclusive, semi-exclusive or exclusive basis
 - **Cross-licensing** with a 3rd partner - if required
 - **Divestiture** of the project
 - **Merging** with a partner to strengthen the position for the commercialisation of the project
 - **Acquisition** of a partner whose activities fit into client's business strategy for the project
 - Search for a highly motivated **distributor**
 - To **initiate contacts** and to manage the whole process

Service Costs

DHC is open to discuss the charges for its services dependent on the topics asked for by the customer.

Work may be charged per hour or per day. A fixed amount may be agreed upon for very well specified tasks.

DHC is also willing to work on the basis of a fixed monthly or yearly consultancy-fee.

Regarding divestitures, mergers or acquisitions DHC is also willing to work solely on a success-fee basis with - by the customer approved - travelling and other travelling related expenses paid ahead.

In this case however, DHC will ask for an exclusive assignment of the "project" for a certain time and for the success-fee payment immediately at closing. The fee will be calculated according to industry standards .

If DHC participates in the development of a project to a product DHC could also consider for its services compensation by royalties after launching of the product
DHC would then not charge for consultancy with the exception of travelling costs.

Who is DHC?

Managing Director: Dr. Hans-Georg F. Eisenwiener

BIOGRAPHY

Dr. Hans-Georg F. Eisenwiener has more than 45 years experiences in the laboratory field.

He received his PhD in physical chemistry from the University of Mainz. By the approval of the Swiss Society for Clinical Chemistry and Molecular Diagnostics he is also a clinical chemist and certified to run a routine clinical laboratory.

Before he entered the Diagnostic Division at F. Hoffmann - La Roche in Basle he was Head of the Clinical Laboratory of the Neurological Clinic at the University of Göttingen. In Göttingen he worked also on a private lecturer (Privatdozent) work (not finished) about Encephalitis dissiminata (Multiple Sclerosis).

He joined Roche in 1970 and belonged to those persons in the early phase of Roche's Diagnostics Division who shaped with his team the future broad product portfolio of Roche Diagnostics.

Until 1979 he was responsible for Diagnostics' Product Development in Clinical Chemistry and was strongly involved in automation/analyser development. From then on he was responsible for Diagnostics' Research & Development in Basel. He managed up to 120 persons in the broad diagnostic fields of Clinical Chemistry, Immuno-Chemistry, Coagulation and Microbiology. The very broad 1990 menu of reagents for the various analyser-systems has been developed in his R&D teams. All the ideas for Roche's analysers from the methodological point of view were also conceived there under his management.

After Roche's re-organisation and external the acquisition of Boehringer Mannheim GmbH by Roche in 1998/99 he was responsible for the search, identification and licensing-in of new diagnostic analytes and new methodologies / technologies.

During this time he initiated very many clinical evaluations for new analytes with respect to proof-of-principle, clinical sensitivity and clinical specificity in the area of

bone-, cartilage- and joint diseases, cardiovascular diseases, coagulation and thrombotic diseases, tumor diagnostics and neurology field (Stroke, TIA, Epilepsy).

Dr. H.-G. Eisenwiener is experienced in contacting, partnering and contracting and he has proven experiences in bringing projects from R&D to Production and Marketing.

In 1999 after ending his Roche time he started his own consulting company in the same fields he managed already inside Roche, extended by the new coming-up fields of Point-of-Care testing procedures.

He always worked results- and budget oriented in a "participation-and-communication management style" and has the ability to identify needs for changes and to install them.

He has more than 50 publications, was member of the German- as well of the Swiss Society for Clinical Chemistry and Member of the American Association for Clinical Chemistry.

He worked as delegated expert in many working groups of VDPGH, DIN, IFCC, CEN for setting European and International Standards for performance- and clinical utility evaluations, assessment of clinical data, statistics and reliability of laboratory result.

Past and present consulting activities of DHC

After his retirement from Roche he has built up his own consulting company and did consulting service in the whole diagnostic area, presently especially in the immunochemical, Point-of-Care field and in strategic planning.

Some examples:

- Assessment of the potential commercial success of a new clinical chemical analyser (for a funding department of a well-known Canadian bank).
- Consulting and leading a group of scientists being active in the field of new BioSensor-based diagnostic technologies and their automation (for a commercial research institute in Cambridge, UK).
- Assessment and evaluation of the clinical data of a new tumor marker for PSA (for a company in Austria).
- Running courses in diagnostic companies regarding clinical evaluations of new diagnostic analytes, statistics and interpretation of the results.
- Assessment of various tests in the field of dementia and Alzheimer's disease (work for another consultant).
- Consulting regarding Point-of-Care tests and assessment of the commercial success of a small doctor's office measurement system (for a leading international company in Germany, manufacturing medical and healthcare products, which wanted to expand their activities into the diagnostic area).

- Looking, for screening and assessment of new diagnostic markers (for one of the largest diagnostic companies).
- Strategic considerations and establishment of the adequate specifications for BioSensor based Point-of-Care clinical chemical products, especially for a new home blood glucose measurement device with BioSensor strips (for a company in South Korea being active in Point-of-Care BioSensor products).
- Assessment of the commercial potential of markers in the field of bone and cardiovascular diseases (for a Cardiovascular Research Institute).
- Assessment of new markers for myocardial infarction, heart insufficiency, stroke, Alzheimer's disease and other neurological diseases (for a company in Canada).
- Planning of the development and clinical evaluations of functional drinks (for a company in Ireland)
- Assessment and commercialisation activities of a new approach in the field of atherogenesis and arteriosclerosis (for a company in Cambridge, UK).
- Consulting in immunochemical MTP based research, production, QC and immunochemical Point-of-Care testing (for a small diagnostic company in Germany).
- Assessment of the clinical utility- and of the performance data of assays in the cerebrovascular field of ischemic / hemorrhagic stroke, TIA and Epilepsy (for a start-up company in Atlanta, USA).
- Looking for and strategic planning of a product portfolio for doctor's office testing (for a new Point-of-Care company in Germany).

The Team

DHC is a "1-man company".

DHC works - if necessary and asked for by its customers - in a network of associated independent partners and consultants who are highly experienced in market considerations, patent assessments, legal issues, labellings, registration and in the approval process.

DHC will however, only involve associated partners, if the client does agree on that, if the associated partner does not work in the same field for another company thus competing with our client. In all cases confidentiality agreements on the subject have been signed.

These partners are in the US, in Europe and in the Far East.

Imprint

Legal Disclosure

Information in accordance with section 5 TMG

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