





A little bit of History...

Oriens was born with the goal of presenting a new concept in CONSULTING SERVICES to the market. With this purpose in mind, our differential is to offer a committed work, along with a strategic business view, totally dedicated to our customers needs.

The team is formed by experienced professionals with multidisciplinary training to provide a full service in health monitoring. Furthermore, professionals within our team gained experience through performance at ANVISA allowing Oriens to offer its customers a differentiated consultancy according to the Health Authorities regulation.

The company logo, as well as the facilities and the customized materials respect a visual identity which focuses on the balance between hot and cold colors. This combination emphasizes a concept of work based on transparency, clarity, security, commitment and dynamism offered to the clients.

Values

Orientation

Knowledge

Experience

Transparency

Safety

Agility

SOLUTION



Diferentials



Technical and regulatory knowledge with strategic business view.

Multidisciplinary Team.

Focus on obtaining positive results in all sectors of activity our customers operate.

Ethics and commitment.

Areas

Pharmaceutical Products
Industries

Health Products Industries
(and other industries alike)

Importing companies

Distribution

Exporting companies

Fractional companies

Health Surveillance Services
companies

*Clinical Testing
Laboratories*



Serviços

Administrative Services;

Preventive counseling;

*Adaptation, licencing and company
authorization;*

Product registration at ANVISA;

Quality management;

Avertising monitoring;

Legal advice;

Importation and exportation;

*Stability studies and degradation
products research*





ADMINISTRATIVE SERVICES

- ⇒ Protocol at the official authorities;
- ⇒ Consularization of documents;
- ⇒ Second copy of processes;
- ⇒ Oriens *Office*: at Oriens Brasilia, our customers have a place to work and perform meetings, which offers computers and internet services.



Process Management System



The consulting services regarding process monitoring and control are now to be performed through a specialized software developed exclusively to inform the progress and status of deadlines and company operations. The SGP was designed based on the highest standards of safety and offers restricted and controlled access. Therefore, it is extremely safe and reliable.

Thus, SGP provides Oriens clients with process monitoring and also data portability available for meetings or national and international travels.



PREVENTIVE CONSULTING

- ⇒ Development of reports on the status of all the company products regarding current legislation and presentation of proposals for corrective actions;
- ⇒ Evaluation regarding accuracy of the information on the package, label, label leaflet/instructions of use, following the current Health Legislation and the Consumer Defense Code;
- ⇒ Quality audit for verifying the implementation of the Good Practice and health demands, as well as identifying and presenting solutions on improving facilities, documents and technical aspects.
- ⇒ Newsletters reporting new regulations, news, orientations when necessary, as well as technical and legal advice;
- ⇒ Training and courses for development of human resources in order to adapt the companies and their products to the health standards.



COMPANY ADAPTATION AND LICENSING

- ⇒ Company Working Permits to manufacture, import and distribute;
- ⇒ Advice and preparation of written procedures (Standard Operational Procedure) to all processes performed for companies under health evaluation.
- ⇒ Performance of Quality Audit including technical orientation regarding Good Practices in the facilities/manufacturing lines in order to achieve the ANVISA Good Practices Certification;



COMPANY ADAPTATION AND LICENSING

- ⇒ Technical orientation to validate processes, systems and methods, including development of Validation Master Plan and its protocols;
- ⇒ Contracting Services: to evaluate the possibility of contracting services according to the health legislation, to notify and follow up its legalization process at ANVISA;
- ⇒ Health License Renewals, Company Working Permits and Good Practices Certificates.



PRODUCT REGISTRATION

- ⇒ Preparation, evaluation, review, and processes protocol registration at ANVISA in order to regulate the product;
- ⇒ Monitoring the process and development of priority analysis requests according to the current legislation;
- ⇒ Registration renewals: to monitor deadlines and to develop processes according to health legislation;
- ⇒ Alterations, inclusions, post-registrations, cancellations and recourses, along with legal knowledge;
- ⇒ Packaging, labeling and instructions of use: to develop the written material according to the current Health Legislation and the Customer Defense Code;



QUALITY MANAGEMENT - Consultancy and Technical Advice

- ⇒ Quality Systems Implementation - ISO 9001:2000, ISO 13485:2003, ISO 17025:2005;
- ⇒ Administration of Quality Systems;
- ⇒ Unifying Certifications regarding Quality on Manufacturing Good Practices;
- ⇒ Organization of Processes Management;
- ⇒ Project and Implementation of Participative Programs - 5S's, Development Groups, amongst others;
- ⇒ Project and Organization of the Work - Layout Design decisions, Methods and Processes Studies, amongst other activities focused on Industrial Planning and Production Systems;



QUALITY MANAGEMENT - Training in Company

- ⇒ Quality Tools;
- ⇒ MASP - Problem Solving and Analysis Methodology;
- ⇒ Process Management and Approach;
- ⇒ Interpretation of Standards ISO 9001:2000, ISO 13485:2003, ISO 17025:2005;
- ⇒ Non-conformity Assessment Methodologies and Improvement Opportunities;
- ⇒ Training of Internal Auditors according to Standards ISO 9001:2000, ISO 13485:2003 and ISO 17025:2005;
- ⇒ Statistical Process Control;
- ⇒ FMEA -Failure Mode and Effect Analysis + Control Plan.



QUALITY MANAGEMENT - Training and Development

⇒ Training and courses for development of the companies and their staff in order to adapt its products and processes to the Health Regulation.

QUALITY MANAGEMENT - Auditing

⇒ Internal Audits and Audits in suppliers based on standards ISO 9001, ISO 13485, ISO 17025 and ISO/TS 1694, in addition to health normatization applicable to Medication, Health Products, Cosmetics and Sanitizing Products.



ADVERTISING MONITORING

- ⇒ Previous analysis of advertising material, before they are presented at the media, in order to adequate them to current legislation;
- ⇒ Monitoring and notifications regarding administrative processes, providing necessary defenses and recourses;
- ⇒ Dispute resolutions in case of suspension of advertisements;
- ⇒ Technical and legal advice, as well as assistance in matters concerning both the new and the current legislation.



Legal Consulting and Administrative Regulation

- ⇒ Work performance in partnership between the Regulatory and Legal Departments at the company, so as to assist the clients on both practical and documental aspects concerning Health Law;
- ⇒ Legal Advice regarding the procedures for medication registrations, renewals, alterations, inclusions, cancellations, recourses, transfer of ownership, as well as orientations about the ANVISA structure and operation;
- ⇒ Defense and Recourses regarding Standard Violation Reports at ANVISA (concerning its different areas), other health authorities, consumer defense authorities, amongst others;
- ⇒ Administrative recourses as a result of rejections, cancellations, suspensions, bans, seizures, amongst others;



Legal Consulting and Administrative Regulation

- ⇒ Assistance in replying and/or rejecting notifications from ANVISA supervisions;
- ⇒ Monitoring health legislation and its interpretation as well as Public Consultation, concerning ANVISA;
- ⇒ Evaluation and organization regarding legal and health documents to be sent to ANVISA, such as reports, legislation interpretations and contributions in Public Consultations, amongst others;
- ⇒ Representation of the company at ANVISA regarding legal matters, when necessary;
- ⇒ Management and process monitoring at ANVISA, aiming assistance in technical areas and minimizing weak points.



Legal Consulting

- ⇒ Filing suits for legal processes and monitoring the developments, such as Security and Preliminary Measures, acting at all levels of jurisdiction;
- ⇒ Monitoring the Doctrine and Jurisprudence on the subject.



STABILITY STUDIES AND DEGRADATION PRODUCTS RESEARCH

- ⇒ Orientation and supervision regarding researches to be performed in the company laboratories;
- ⇒ Supervision regarding services performed by subcontracted laboratories;
- ⇒ Development of the Technical Report to be sent to ANVISA, mentioning the mechanisms of formation of possible PDs (Degradation Products), backed by scientific literature;
- ⇒ Support to the supervisors on the development of analytical methodologies indicating stability and PD evaluations;
- ⇒ Support to the regulatory staff on preparing the technical defenses regarding processes at ANVISA;
- ⇒ Training in Company.



IMPORTATION AND EXPORTATION

- ⇒ Development of processes for obtaining importation licenses (LI) and exportation licenses, exportation authorization certificates (FREE SALE);
- ⇒ Approval of import permit for products with special control (such as narcotic, psychotropic, and others; subject to special control , or not subject to health evaluation.