OMICS Group is an amalgamation of Open Access Publications and worldwide international science conferences and events. Established in the year 2007 with the sole aim of making the information on Sciences and technology ‘Open Access’, OMICS Group publishes 500 online open access scholarly journals in all aspects of Science, Engineering, Management and Technology journals. OMICS Group has been instrumental in taking the knowledge on Science & technology to the doorsteps of ordinary men and women. Research Scholars, Students, Libraries, Educational Institutions, Research centers and the industry are main stakeholders that benefitted greatly from this knowledge dissemination. OMICS Group also organizes 500 International conferences annually across the globe, where knowledge transfer takes place through debates, round table discussions, poster presentations, workshops, symposia and exhibitions.
OMICS International is a pioneer and leading science event organizer, which publishes around 500 open access journals and conducts over 500 Medical, Clinical, Engineering, Life Sciences, Pharma scientific conferences all over the globe annually with the support of more than 1000 scientific associations and 30,000 editorial board members and 3.5 million followers to its credit.

OMICS Group has organized 500 conferences, workshops and national symposiums across the major cities including San Francisco, Las Vegas, San Antonio, Omaha, Orlando, Raleigh, Santa Clara, Chicago, Philadelphia, Baltimore, United Kingdom, Valencia, Dubai, Beijing, Hyderabad, Bengaluru and Mumbai.
Mexico and Brazil:  
Lands for bioequivalence testing and generic product registration  
IFaB as a choice for your trials  

6th World Congress on Bioavailability & Bioequivalence: BA/BE Studies Summit  
Aug 17-19, 2015 Chicago, USA
Content

- Who are we
- Our Vision
- Our Mission
- Our Purpose
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Who We Are

IFaB comprises of a team of highly qualified and renowned professionals with various areas of expertise related to medicines.

The team has over ten years of wide-range experience working together while also offering a distinctive approach to clinical pharmacology and bio-pharmacy.

IFaB is an organization dedicated to providing research, training and technical-scientific support to the pharmaceutical industry, both domestically and internationally.

We provide top-quality services for the development of new drugs from both the biopharmaceutical, as well as the clinical pharmacology perspective.
To consolidate IFaB - even further - as a professional research and development organization, with a global presence and strong commitment to its partners, employees, customers and stakeholders.
Our Mission
Our Mission

To provide professional scientific and technological services to the pharmaceutical industry.

Our **objective** is to encourage the development of highly-effective and safe drugs of demonstrated quality, achieved through the use of highly specialized, technological and human infrastructure that meets international technical, scientific, regulatory and ethical standards.

Our **mission** is to protect the public against health risks produced by the use and consumption of health products and the occurrence of emergencies through the regulation, control and prevention of health risks.

The well-being of our volunteers is **our first priority** and the foundation to our mission and ethical commitment.
Our Purpose
Our Purpose

To respond to the needs and requirements for research and development of new drugs, as well as the validation processes of generics and new combinations.

To respond to the harmonization and regulatory processes being implemented worldwide.

To contribute to the development of bio pharmaceuticals and clinical pharmacology locally, regionally and globally.
Our Goals

1. To become the first choice and preferred partner in early phase clinical pharmacology units and bio pharmaceutical companies on both a national and global level.

2. To continuously train our competitive human resources to serve our clients in a timely and efficient manner.

3. To continuously enhance our facilities to improve efficiency and provide our clients with accurate results.
Management Overview
Management Overview

A Highly Experienced Management Team

Marlene Llópiz, BA, MD, MPH - CEO

Dr. Llópiz holds a degree in biochemistry from Austin College, an MD degree from the Universidad Anahuac and a Master in Public Health degree from the Harvard University School of Public Health. She was president of the Association of Medical Specialists in the Pharmaceutical Industry, is a honorary member of the CPhI Advisory Board, Secretary General of IFAPP, etc. She has received several national and international honor awards and is currently, a finalist for the Lifetime Achievement Award for Eye for Pharma. She has written several articles and books on clinical research and pharmaceutical medicine. She has over 20 years experience in contract research organizations including being Country Manager at Quintiles, ICON and Venn Life Sciences. She hold ACRP and RAPS certificates.

Federico Arguelles, MD, MS – Clinical Operations Director

Dr. Arguelles is the Ex-Commissioner for the National Regulatory Agency in Mexico (COFEPRIS). He is a highly experienced physician in regulatory affairs, clinical operations and international strategies for all types of trials in both Mexico and abroad.

Luis Garcia - Analytical Area Director

Mr. Garcia holds a Masters Degree in Biopharmacy. He has wide experience in the development and validation of bio-analytical methods, as well as in pharmacokinetics and biostatistics. He is a member of several national and international scientific societies.
High Qualified Team

IFaB / 71 employees

- Health Sciences: 68%
- Support Areas: 32%

- PhDs & Masters: 6 employees
- Physicians: 7 employees
- QFB’s: 24 employees
- Technicians: 4 employees
- Others: 7 employees

Management

<table>
<thead>
<tr>
<th>NAME</th>
<th>ROLE</th>
<th>Education</th>
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<tr>
<td>MARLENE LLOPIZ</td>
<td>CEO</td>
<td>Master Degree in Public Health, Medical Doctor, Bachelor of Science in Biochemistry</td>
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<tr>
<td>LUIS GARCIA</td>
<td>ANALYTICAL DIRECTOR</td>
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<td>ISABEL RUIZ</td>
<td>ANALYTICAL SUBDIRECTOR</td>
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<td>CLAUDIA LARA</td>
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<td>LIZ MEDINA</td>
<td>PHARMACOKINETICS SPECIALIST A</td>
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<tr>
<td>JAIME PONCE</td>
<td>BUSINESS DEVELOPMENT</td>
<td>MBA</td>
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</table>
IFaB is a Complete Provider of Clinical Services

Deliveries with global quality, price competitiveness and aligned to timelines and budget

Clinical Research Services
- Phase I, II and III
- Pharmacoeconomics
- Pharmacovigilance
- Medical Writing

Consulting services
- Regulatory
- Scientific
- Commercial

Team Work / Value Added

Based on a highly qualified and professional team, IFaB collaborates with our sponsors to increase the possibility of the success of their projects

Regional 3rd Authorized Party BE, PK PD
Our Business

At A Glance

1. ~15% Market Share
2. 2 Certifications
3. Analytical + Clinical + QA Areas
4. Over 70 Employees
5. 40 Studies in Pipeline
6. 70 Studies in Backlog

1 Representative of the total number of projects from 3Q14 to 1Q15
**Worldwide Experience – Cofepris / Anvisa Strategy**

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<tr>
<th>Sponsors</th>
<th>Special needs – Best practices knowledge are incorporated in SOP’s</th>
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<tr>
<td>Local Pharma</td>
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<tr>
<td>Regional / Global</td>
<td>• Global Expansion Strategies</td>
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<td>CRO’s</td>
<td>• Aggressive timelines</td>
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<td>Gx Corps</td>
<td>• SOPs, Global Communication,</td>
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<td>• Global Quality Standards</td>
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<td>• Homologated Analytic Methods, Follow up across the Complete Process</td>
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</table>

- Sponsors
- HQ and Legal Affairs rep.
- Potential new markets
Our Business

Clinical Pharmacology Services

- Bioequivalence
- Bioavailability
- Concept Trials
- Phase I
- Early Phase II
- Pharmacovigilance
- Pharmacoeconomics
- Pharmacokinetic Studies
Our Business

Biopharmaceutical Services

- Bio-statistical analysis
- Dissolution profiles to test for interchangeability and for bio-waivers
- Development, validation and application of bio-analytical methods for the quantification of drugs, biomarkers and biotechnology drugs in biological matrixes
Our Business

Experience

> 300 Studies
Over 20,000 volunteers

Over 8 Phase II studies

> 150 Validated Bio-Analytical Methods

More than 13 Phase I studies

> 110 Bioequivalence studies
> 20 Bioavailability studies
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</table>
Our Business

Facilities

- **Clinical Area**: One of the largest clinical areas in the country, with over 80 beds, medical offices, a phlebotomy area and medical contingency zones.

  It also has diagnostic and emergency equipment, including defibrillators, transfer equipment and monitors.

- **Analytical Area**: Equipped with state-of-the-art technology enabling the company to perform highly complex studies. There are also sample extraction, reception and storage areas.

- **Quality Control Area**: There is an independent area where quality management takes place ensuring that the highest standards are consistently achieved and any arising risks are properly managed.
Our Business

Opportunities

- Concept Testing
- Phase I
- Early Phase II
- Phase II
- Phase III
- Phase IV
- Commercial
- Healthcare Delivery

- Clinical & Project Management
- Clinical Trial Support
- Product Development Consulting
- Observation & Concluding Phase
- Market Consulting
- Full Service CRO

- Our Clinical Pharmacological Offering - Today
- Our Clinical Pharmacological Offering - 2015
- Our Clinical Pharmacological Offering - 2016
Certifications

• Certified by COFEPRIS, the Mexican Health Authority.

• Certified by ANVISA, the Brazilian Health Authority.
• IFaB is the only non-Brazilian company in America that has an ANVISA certification for clinical, analytical studies and statistics.
Initiatives

Social initiatives: Generic equivalents of brand-name drugs allow lower income individuals to have access to treatment that can save or improve the quality of their lives.

IFaB is delivering to society by reassuring the quality of generics that become accessible to people at the bottom end of the socio-economic ladder.

Environmental initiatives: The company has also taken distinct steps toward monitoring its environmental impact by hiring an expert in the topic.
CEO’s Message
CEO’s Message

IFaB has grown tremendously over the last decade and will continue to do so over the next few years.

Much of our success has been and is attributed to our team’s experience, commitment and desire to positively contribute towards our society, clients, and stakeholders by **upholding the highest standards in the pharmaceutical industry**.

Going forward, the delivery on our promises, goals and visions will continue to play an instrumental role in achieving further success so that together we can continue on the road to achieving sustainable and continued growth.

MARLENE LLOPIZ
CHIEF EXECUTIVE OFFICER
Thank you
Let us meet again..

We welcome you all to our future conferences of OMICS International
7th World Congress on
Bioavailability & Bioequivalence: BA/BE Studies Summit
On
August 29 - 31, 2016 at Atlanta, USA

http://bioavailability-bioequivalence.pharmaceuticalconferences.com/