

Progenika Biopharma, A Grifols Company

UPV/EHU, 19 de febrero 2014

Progenika Biopharma

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Mission & Vision



Vision

Become a WW leader on selected niches of the IVD market, by developing and manufacturing cutting edge solutions,

... , aligned and supporting Grifols Strategy, ...

.... and ultimately improving Health Care and Human Welfare

Mission

- Set-up a lean organization to launch and serve timely, reliable and robust IVD products and testing services
- Leverage on current capabilities to be a Scientific Reference
- Provide opportunities for professional growth

Background

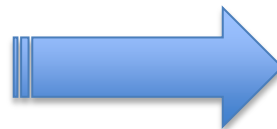
Created from the “scratch” to become part of Grifols Diagnostics Business

Apr 2000 Founded by a group researchers coming from universities and biotech companies

May 2004 CE mark of our first product

Mar 2008 Launching of our first product
in Blood Typing: **BLOOD**chip

Feb 2013



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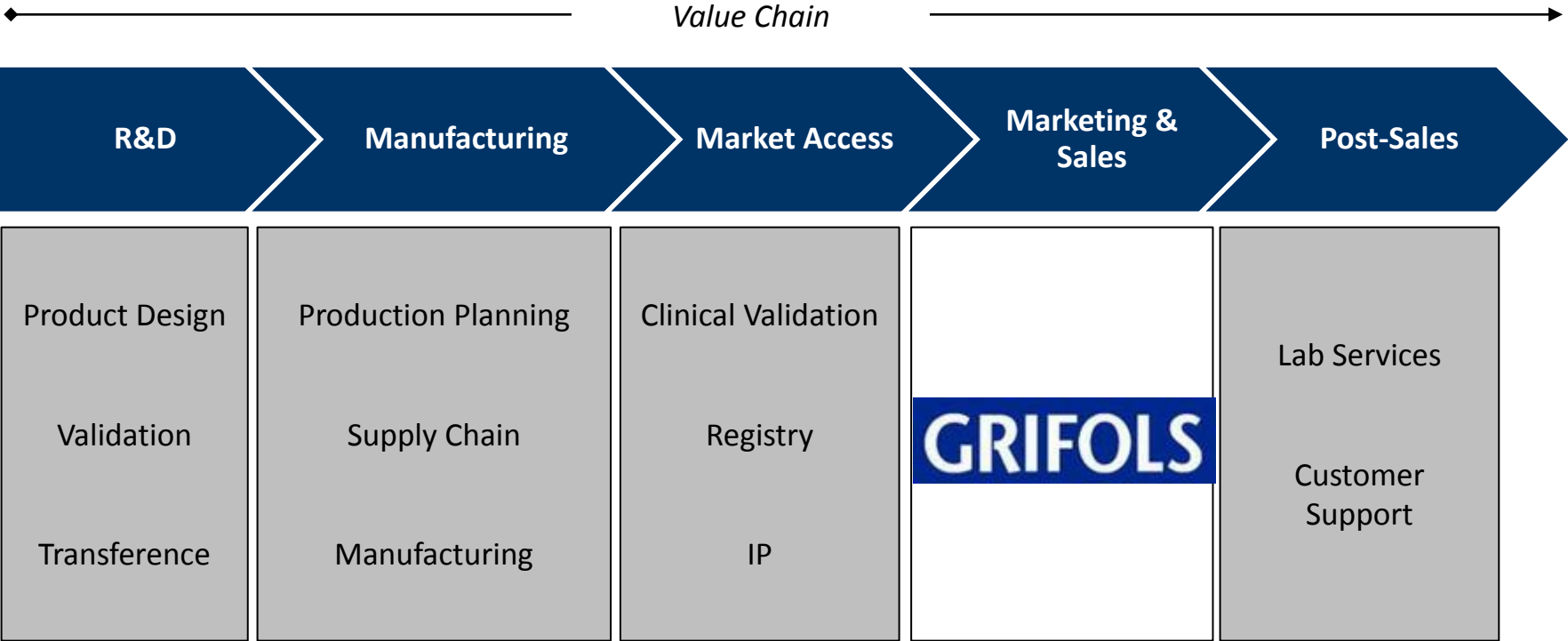
Areas of activity

Progenika specialize on selected niches of activity

Molecular Diagnostics	Blood Typing	Blood Group Genotyping (BGG)
		HLA Typing
		ID Serology (<i>Proteins – Proof of concept</i>)
	Selected Inherited Diseases	Cardiovascular - FH
		Respiratory - A1AT Deficiency
	Specialized Tests	Laboratory Testing Services (SGF, Nutribeads, Alzheimer, others)
Immuno- chemistry	Immunology	Biological drugs Monitoring - Promonitor
		High-Value ELISA tests for Triturus

Business Model

Focus On Our Core Capabilities to Provide Competitive Advantage for the Group



Facilities

First-Class Laboratories for R&D, Lab Services and Manufacturing (I)



- ✓ Inaugurated in Feb '09
- ✓ 2,500 squared-meters
- ✓ Fully-owned by Progenika

R&D Laboratories – 520 m²

- Sample Preparation & Extraction Lab
- Pre-PCR Lab, Reagents Lab, General lab, Bioinformatics Unit, Culture laboratory
- Dark and Cold room (4°C)
- Sample storage room (-80°C & -20°C)

Laboratories for Service Testing – 120 m²

- +3,000 Samples/year tested for diagnostic purposes; +5,000 Samples/year for Research Projects

Facilities

First-Class Laboratories for R&D, Lab Services and Manufacturing (II)



Manufacturing Facilities – 420 m²

- DNA-chip, Reagents for DNA-based kits, Reagents for Protein-based kits, Auxiliary mat.
- Packaging area
- Storage Room
- Cold Rooms (2°C - 8°C)
- Room-controlled Conditions

Installed capacity can absorb the expected growth on manufacturing volumes

- Estimated capacity for Beads-based Products – 24 lots of 88 kits/each = 2,112 kits
- Estimated capacity for DNA-Chip based Products – 12 lots of 17 kits/each = 204 kits
- Estimated capacity for ELISA based Products – 106 lots of 100 kits/each = 10,600 kits

Further growth would require feasible changes as increasing Lot Size, double-shift or include a second manufacturing line

Facilities

Committed with the Highest Quality Standards



Quality Control Area – 60 m2

- Sample preparation room
- Sample analysis room

Quality Assurance System in-place

Facilities Certified by Ministry of Health for IVD production

Facilities & Processes under ISO 13485 (2011), ISO 9001 (2005)



GMP compliance for Manufacturing facilities

Products with CE-mark certification

CLIA-Lab and CAP accreditation


Credentials

A Reference on Molecular Diagnostics and Proteomics (I)

Area	Patents	Publications	Presentations at Int'al Forums
	6 Patents Granted 5 Patent Families Requested	11 peer-reviewed <ul style="list-style-type: none">• Transfusion Medicine and Hemotherapy• British Journal of Haematology• Transfusion Clinique et Biologique• Vox Sanguinis	+20
	5 Patents Granted 2 Patent Families Requested	6 peer-reviewed <ul style="list-style-type: none">• Atherosclerosis• Journal of the American College of Cardiology• Clinical Chemistry	+13
Other Genomics	11 Patents Granted 13 Patent Families Requested	19 peer-reviewed <ul style="list-style-type: none">• Pharmacogenomics• Gastroenterology• Translational Research• Clinical & Translational Oncology• Clinical Cancer Research	+50

Credentials

A Reference on Molecular Diagnostics and Proteomics (II)

Area	Patents	Publications	Presentations at Int'al Forums
	1 Patent Family Requested	5 peer-reviewed <ul style="list-style-type: none">• Annals of Rheumatic Diseases• Rheumatology• Clinical Chemistry and Laboratory Medicine	+15
Other Proteomics	1 Granted 1 Patent Family Requested	8 peer-reviewed <ul style="list-style-type: none">• Journal of Proteome Research• Journal of Biological Chemistry• Human Reproduction	+15

Credentials

A Reliable Partner on International Research Consortiums



International Projects

- 4 Projects awarded on the EU V Framework Program – 10 Int al Partners on average
- 11 Projects awarded on the EU VI Framework Program – 14 Int al Partners on average
- 11 Projects awarded on the EU VII Framework Program – 10 Int al Partners on average
- 8 Projects on ERANET and Eurostars Programs – 4 Int al Partners on average
- Preparing dossiers for the EU Horizon 2020 Program



National Projects

- 4 Projects CENIT awarded
- 5 Projects INNPACTO awarded
- 10 Projects awarded by CDTI



Local Projects

- 8 Projects ETORGAIS awarded
- +20 Projects awarded by Basque Government and other local institutions

What makes Progenika exceptional?



A First Class Human Team

- Talented
- Multidisciplinary - Biology, Chemistry, Pharma, Medicine, etc
- Diverse - 5 different nationalities
- Committed with the project and with ambitious to excellence



Constant Innovation

- 50% of annual turnover dedicated to R&D activities
- Collaboration with leading research centers and KOLs



Business Focus

- Specialized on selected niches of activity
- 4-5 indications; Genomics and Proteomics; 2-3 technologies
- Clear Business Model
- Focus on our key competitive advantage (R&D and production)

Progenika's Team

Diverse and Highly Qualified (I)

Headcount Jan '14 = 85

Average Age

37 Years-Old

Seniority

6.5 Years

Country of Origin

5 Nationalities

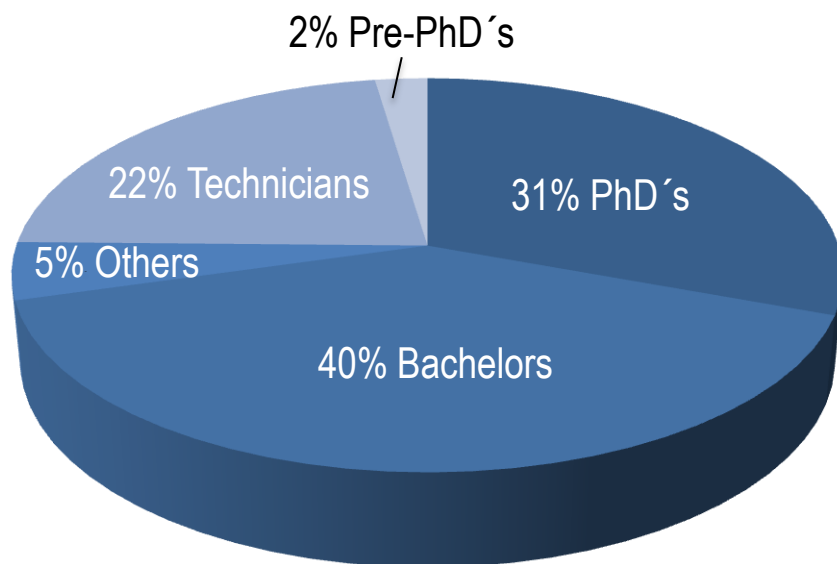
Gender

67% Women

Progenika's Team

Diverse and Highly Qualified (II)

Staff Distribution by Academic background



FTE Jan'14 = 85

International Universities of Origin

- University Of California, USA
- California State University, USA
- University of Southern California, USA
- National Institutes of Health, UK
- University of Reading, UK
- University of Leicester, UK
- University of Surrey, UK
- University of Strathclyde, UK
- Universidad de Bordeaux, France
- Universidad de Odense, Denmark
- Universidad Nova de Lisboa, Portugal
- Universidad de Coimbra, Portugal
- Universidad Abdelmalek Essaadi, Morocco

Progenika's Team

Project Leader



- 27 – 30 Years Old
- PhD. Molecular Biology
- 1st job
- Academic Experience
- High Level Qualifications
- Research Centers
- Back Home
- Technical abilities

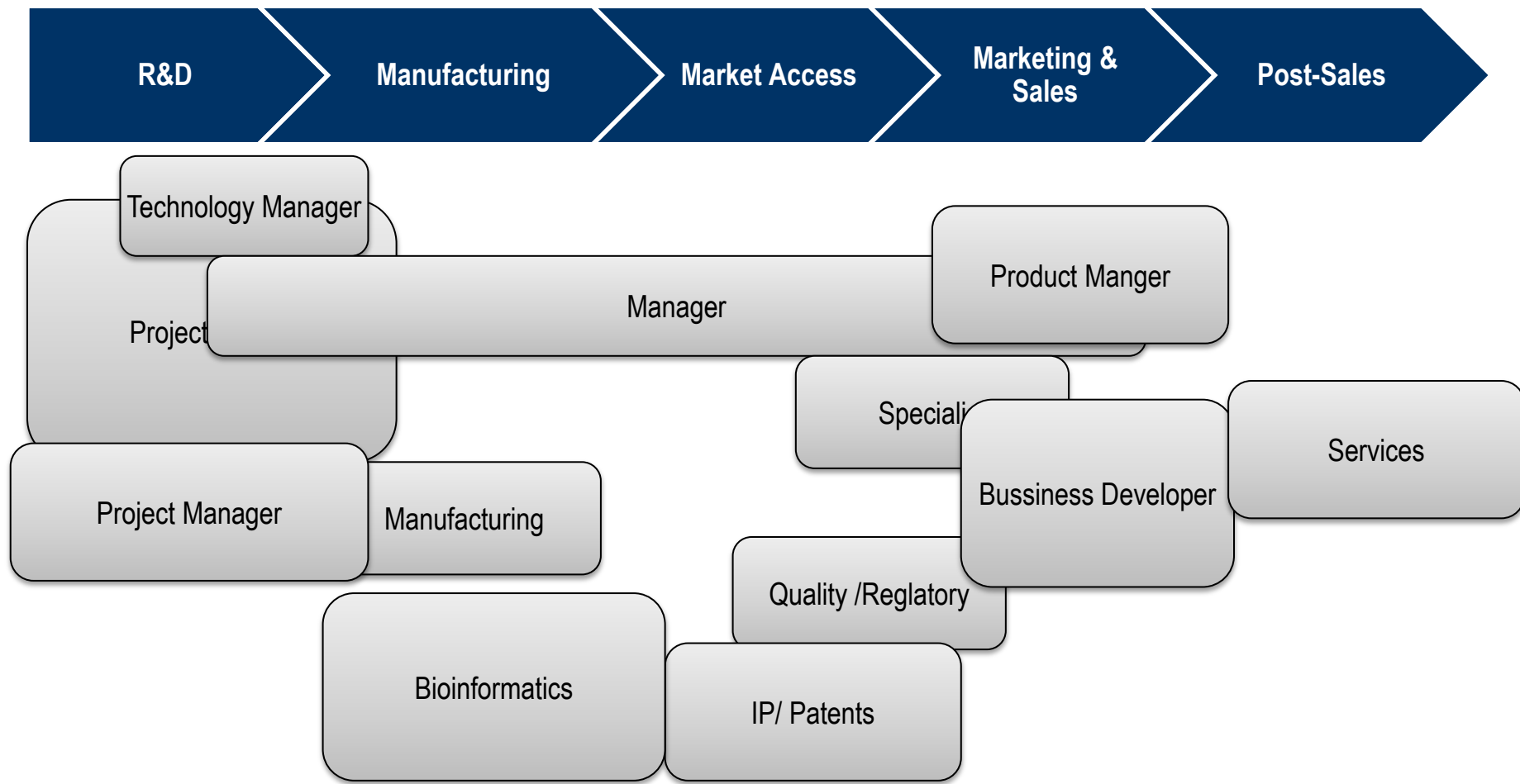


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Progenika's Team

Professional Career



Opportunities

Profiles required by area

- **R&D**

- Scientifics (PhD; Bch)
- Specialists
- Fellows
- Bioinformatics
- Technicians
- IT systems
- Product Development
- Intellectual Property
- Lab. Manger

- **Manufacturing & Services**

- Bachelor (Master)
- Technicians
- Quality Control

- **Technical Area**

- Regulatory affairs
- QA/ QC

- **Management**

- Process
- Grants
- Projects
- Everything

- **Sales & Marketing**

- Bachelor (Master)
- Technicians
- International
- Customer Service

Opportunities

Go on searching...



- Qualified Professionals: Value of the company
- Candidates well focused
- Giving solutions (youngest: enthusiasm, commitment, talent)
- English (at least,...)
- Training - Specialization
- Open-minded
- Versatility and multidisciplinary
- Team players
- Skills
- and International Experience!!!!

Progenika Biopharma is a Grifols biotech company focused on the development of technology for personalized medicine that designs and manufactures cutting edge solutions for the in vitro diagnosis market, improving Health Care and Human Welfare. Progenika Biopharma is a pioneer in the development of molecular biology tests for studies of transfusion compatibility.

Progenika Biopharma is looking to strengthen its Quality Team in Derio, Bizkaia, with a

QA/RA professional

Candidates must have a university degree in biological sciences and professional experience gained within the pharmaceutical, biotechnology or medical device industry; Knowledge of ISO 13485, GMPs, CE-mark and FDA regulations; Ambitious, achievement-oriented and reliable collaborative team player; Well structured working style combined with excellent communication and interpersonal skills. Fluency in English is a mandatory.

Reporting to the Technical Director, the candidate will be responsible for participating in Quality Assurance related activities, such as DHR review and lot release; Writing GMP and regulatory relevant documents related to product quality ; Providing support and be actively involved in internal audits; Participating in Regulatory Affairs related activities, such as definition of regulatory strategy, reviewing of validation studies and other regulatory submissions documents; and assisting the other departments in applicable guidance for validation studies

You may send your CV and letter of intent to:
gorka.ramirez@progenika.grifols.com

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Eskerrik Asko!

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