

# Enrique Blanco

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## Gral Director on Operations /Chief Operation Officer / Sr. Ops Director / Pharmaceutical Technical Ops / Sanitary Regulatory Expert

*Hands on Technical Leader , motivator and results Oriented production & Supply Chain expert.*

General Operations Director, Bilingual, experience of >30 years in the pharmaceutical operations, regulatory affairs Quality & R&D, managing > 900 people, Net sales 1000 Mn MxP, Net profit improvement on 148% (6% to 11%), COGS reduction 19% (67% to 56.4%), 8 Mn USD on expenses, > 35 Mn USD of inventory level/Procurement and Capital expenditure projects > 30 Mn USD, up to 5 Mfg sites, people management and development plans and process improvements (Lean Mfg), Supply Chain and Procurement on Pharmaceuticals & Cold chain, Production experience on Parenteral forms, Oral dosages, Topic & High Potent dosage forms, in a highly regulated environment (FDA, EMA, COFEPRIS, ANVISA, INVIMA, DIGEMID, SENASICA, etc). strong background in leadership, motivating & developing people and managing fast-paced operations, financial awareness, multitasking operations, time management, verbal and written communication skills.

### STRENGTHS

- Leadership & Strategy Implementation
- Team Building skills
- Complex Operations Mgmt
- Behavior based on Quality & Safety
- People Development
- Cost-Effective focus
- Staff Management & Motivation
- Operations Efficiency & Lean Mfg
- Customer Satisfaction

### CAREER SUCCESS

#### *Grupo Loeffler – Russek, Mex*

**General Ops Director / Corp Operations Director.**

Nov/2021 to Mar 2024

Responsible of Laboratorios Russek P&L and Entire Pharma Operations at the group on Mfg, Eng/Projects, Quality, R&D, Regulatory Affairs and Operations excellence on the Sterile, Oral Liquids & Solids facilities, Supply & Procurement Processes strategy development and budget delivery & implementation, New Product launches and capital projects implementation, efficiency improvements & CMO/CDMO projects & Supply.

#### Delivered Results:

Net Sales 1000 Mn MxP, Net profit from **+6% to +11%**, COGS **reduction 19%** (67% to 56.4%),

GMP's renewal project, to provide supply continuity on Products revenues **+1000 Mn MxP**

Formula Optimization & Marketing Authorizations renewals, Several Projects and Tech Transfer to support supply and compliance (API,Mfg site Chg, Cost Improving). CMO supply & new projects to improve the Cost Absortion, New Product Launches of 1+ Million MxP & R&D process implementation & one patent s.

S&OP process implementation & Inventory Control, improvement on coverage for Impulse channel.

Cost variations reduction on COGS impact (+\$500 TUSD per year)

Overall Equipment Efficiencies, improving Mfg & Pkg productivity operations. **+15% volume & -33% cost (2Yr)**

COGS & Conversion Cost Savings Projects of 500-1000 KUSD/ Year, Capital expenditure projects +0,5-3 Mill USD

Regulatory Marketing Authorizations maintenance and new submissions & remediations

## ***Lupin Mexico – Lab Grin, Mex***

### **Operations Director.**

Feb/2018 to Jul/2021

Responsible of Mex Site on Mfg & Packaging, Quality, R&D, EHS, Eng, Regulatory Affairs and Operations excellence on the Sterile Ophthalmic and Solids facilities, strategy development and budget delivery & implementation, New Product launches and capital projects implementation, efficiency improvements & CMO/CDMO projects.

#### **Delivered Results:**

GMP's renewal project >**7,6 Mn USD**, to provide supply continuity on Products revenues **800 Mn MxP**  
Formula Optimization & Marketing Authorizations renewals (1<sup>st</sup> sales product renewal after 10 yr recovered)  
Several Projects and Tech Transfer to support supply and compliance (API Mfg site Chg, Cost Improving).  
GMP certification renewal on Peru & México – DIGEMID & COFEPRIS (PICS)  
New Product Launches of 1 Million USD & R&D process implementation & one patent submission  
S&OP process implementation, New products launches & Countries integration & Inventory Control.  
SAP Cost variations reduction on COGS impact (+\$500 TUSD per year)  
Overall Equipment Efficiencies, improving Mfg & Pkg operations  
COGS & Conversion Cost Savings Projects of 500-1000 KUSD/ Year  
3 consecutive years delivering below budget (5-10%).

## ***PiSA Farmaceutica, Mex***

### **Solids, High Potent & Agro Plants Director.**

Aug/2015 – Feb/2018

Responsible of Mfg & Packaging Proceses On the three facilities (Agropecuarian products, Antibiotics, High Potent and General drugs, budget, launches and capital projects implementation, efficiency improvements.

Contruction of >30 Mn USD Agro Pharma products

#### **Delivered Results:**

Get the GMP certificate with no GMP observations for Colombian products (INVIMA), GMP's recertificación for México,  
To Provide continuity on all Pharma and high potent products revenues **22 billion MxP**  
Improve the service level from below 60% up to 90% in 4 months  
High potent & Pharma facility refurbishing to update the GMP's at the plant  
Implement KPI and lean techniques on Agro, Antibiotics facilities and High potent & Pharma.  
Improve the labor cost on processes at Pharma  
Develop and deploy the Oral Solid Dosage Forms Strategy for the Company, and support for the new solids and liofilization products facility and startup, tech transfer activities.  
Construction & Qualification of an Agropecuarian Drug products facility of 30 Mn USD.

## ***Stern Pharma GMBH, Mex***

### **Operations Director Sterile Processes.**

Aug/2014 – Aug/2015

Responsible of Mfg & Packaging Sterile forms, budget, launches and capital projects implementation, efficiency improvements.

#### **Delivered Results:**

Get the GMP certificate with no GMP observations - Provide continuity on Sterile Operations  
Develop customers & Signed medium-long term contracts for Mfg (>5 customers)  
Energy savings Projects (natural gas, electrical source reducción Projects) 25% savings

Performed reorganizational Structure to improve productivity linked to MBO and Technical Training.  
Deployed reliable training matrix to support GMP & operations.

### *LUGAN CHEMIE, MEXICO, MX*

#### **Pharmaceutical Operations Consultant, Ops Director**

Jan/2014 – to today

Supporting the Pharmaceutical companies on Operations/ Supply and Quality strategies, execution plans and follow up to ensure reliable Production and Supply of Pharmaceutical products. New portfolios proposals and API sourcing

#### *Delivered Results:*

- Supported to get the GMP certificate. & Supply continuity on API sourcing
- Remediation projects to comply cGMP's.
- Training course on NOM 059 SSA 1 2013
- Enfarma publication on Pharmaceutical Operations Articles

### *NEOLPHARMA, Mexico, Mx*

#### **Solids Plant Director-Full time Consultant**

Jul/2013 –Dec/2013

Responsible of Mfg & Packaging Solids, Semisolids and liquids forms, budget, launches and capital projects implementation, efficiency improvements.

#### *Delivered Results:*

- Supported to get the GMP certificate with no GMP observations to support **100 Mn USD sales**
- Provided a reorganizational proposal on person el functions and improved productivity 5% linked to MBO
- Reliable training matrix to support GMP & operations.

### *TEVA PHARMACEUTICALS MEXICO, Mexico, Mx*

#### **Sr Operations Director**

Apr/2009 –May/2013

Responsible of all production sites incl. Biotech & Pharma (5) and leading Operations and supply chain, deploy strategy, compliance of Global health agencies to support sales over 30 countries, procuremet and inventory planing, capital projects execution (>8 Mn USD), compliance on EHS guidelines.

#### *Delivered Results:*

- Stand Alone project to create a Pkg facility in the FG's warehouse to have a sustainable and flexible Pkg operation, established a new supply concept in the Pharma trends. Approved by MoH and running. to support future launches of **~15 Mn USD/yr**
- Five facilities construction (in less than a year), (Sterile, OSD and High Potent drugs – Both technologies) Qualification and start up to provide continuity to the business. to **protect 90 Mn USD/yr**
- Facility shutdown 110 HC reduction and remediation action plan proposal >8 Mio USD on CapEx and supply continuity scheme as distributor license and Third Mfg parties, NO impact to the business, protect 80% of **profit 40 Mn USD/yr**
- Plant shop floor engineering improvements to increase capacity at the facilities on Cyto – Sterile technology to cover 20 Mill USD on sales and other successful projects implementation based on SIPOC, VSM tools to improve productivity and decision-making process at managerial levels improved Productivity on **5%**
- Several successful launches to support different countries (Israel, Mexico, Canada, Europe, Eastern Europe and Asian countries) approx **1 Mn USD per product**
- Several Successful Inspections from countries (Turkey, Lithuania, Brasil, Europe, Colombia & Mexico)
- Civil structural crisis due to earthquake, successful management, Quality Lab shutdown and alternative Lab running in 30 days. Protecting **12 Mn USD/month**

- Clean industry certificate by Mexican Environmental authorities & Environmental site released & closed since 2009 to Sale the facility.
- S&OP meeting & ORACLE implementation, increase the service level from 50% up to 90% in one year.
- Close-down a Betalactamic site with no supply, personnel (union) and environmental impacts to avoid continuing losses of **>750kUSD/yr**
- Organizational Turnover (Crisis management) & Swine Flu Crisis management with out impact on supply **12 Mn USD/month**

### *WYETH PHARMACEUTICALS, (PFIZER), Mexico, Mx*

#### **Operations Director**

Jul 2008 – Mar/2009

Responsible of 2 production facilities incl. Milk Mfg & Pharma and leading Operations and supply chain, deploy strategy, compliance of LatAm health agencies to support sales over the region, procuremet and inventory planing, capital projects execution (>4 Mn USD), compliance on EHS rules and Cold Chain logistics.

#### *Delivered Results:*

- Nutritional Plant refurbishing without supply impact Service level above 98%
- Production of a cold chain product in short term to support the Mexican vaccination program 2009. ~80 Mn USD sales value
- Plant restarted after a long shutdown of 3 months (Crisis management), recover a micro contaminated facility to produce ~60 Mn USD
- Multivitamin product support and re-supply after a stability OOS (By Crisis management) 10 Mn USD/yr

### *BOEHRINGER INGELHEIM PROMECO, Mexico, Mx*

#### **Production Director**

Jul/1997 – Jul/2008

Responsible of 2 production facilities Pharma and leading Production and Engineering, execution on Production strategy, compliance of Mexico, Canada and USA health agencies (FDA) to support sales, capital projects execution (>4 Mn USD/yr), support compliance on EHS rules.

#### *Delivered Results:*

- Overall productivity increase & Capacity utilization increased to **save 20 Mn MxN** and Flexibility labor concept implementation baseline and union managing by objectives implementation creating a window of 30% labor cost reduction.
- Several Cost **Savings in Product Yield for 4.3 Mn USD** & Additional savings from re-structuring the Pharma Production operation and include a Managing by objectives and Bonus system at Union level with an impact of **700 KUSD/Yr**.
- FDA post-approval inspection (2007). **None 483 issues**, 3<sup>rd</sup> time consecutive no observations from FDA, reaching the sales level of 250 Mn USD/yr on Exports to USA, FDA Post-approval inspection (2004). **None 483 issues**, 2nd time in a row with no 483 & protecting >250 Mn USD, Health Products and Food Branch Inspectorate (HPFBI) Post-approval inspection. **None Critical issues**. FDA Pre-approval inspection (1998). **None 483 issues** & Start up the solids production facility. 80 products, 150 presentations, Restart the Canadian products deliveries. 7 products to support.
- Business case to reduce the conversion costs up to 25% in a 1 year period, and team & start up preparation
- Increase the Operational productivity by merging the Mechanical function in the Pkg lines, **increase of 10% and cost reduction of 200 kUSD/yr**
- Several Launches and Technical Transfers for Canadian/Mexican/USA markets packaging transferred from Germany & USA. on Global cost savings projects ~20 Mn USD to reach sales of ~100 Mn USD/yr
- Cost Saving Projects \$150 KUSD and Cost Avoidance Projects \$1 Mn USD (Tax classification).
- Yields increments implemented on the Solids plant saving \$120 KUSD, Cost Saving Projects \$300 KUSD

**HOESCHT-MARION-ROUSSEL, (SANOFI AVENTIS), Mexico, Mx**

**Packaging & Production Head**

Sep/1994 – Jun/1997

Responsible of all packaging and Mfg activities at San Angel facility Pharma and leading Production and packaging areas, support compliance of Mexico health agencies (COFEPRIS) and technical transfer execution.

**Delivered Results:**

- Technical transfer of Packaging, Solids and Injectable product processes (site transfer)
- Plant capacity & shop floor control implementation. BPCS version 4.1 to ensure Plant Capacity managements.
- Financial justification and development to improve the packaging of lyophilized products. providing cost savings of 25KUSD/yr

**PROPOVI SA DE CV, Mexico, Mx**

**Management & Financial Advisor,**

Jan/1994 – Sep/1994

Responsible of supporting the management of administrative activities and support the financial strategy.

**DINAMICA INTERNACIONAL AGROPECUARIA, Mexico, Mx**

**Administrative Manager**

Mar/1993 – Dec/1993

Responsible of administrative management

**BRISTOL MYERS SQUIBB, Mexico, Mx**

**Production Head**

Aug/1988 – Mar/1993

Responsible of production on the Pharmaceutical Mfg and Packaging at 2nd shift and leading Production compliance of Mexico.

**Delivered Results:**

- Yields controlling data base development and started up contributing on cost measuring & improvement.
- Direct compression development for a multivitamin's solid product. cost reduction project of 50 KUSD/yr
- Direct compression development for a psychotropic solid product. Cost reduction project of 20 KUSD/yr
- Nonsterile Process Validation at solids area (A.F.M.)

**EDUCATION & CERTIFICATIONS**

**Bachelor of Science, Chemist-Pharmaceutical Biologist**

MEXICAN NATIONAL UNIVERSITY, Mexico, Mx

1984-1988

Universidad La Salle, A.C. "Total Quality"

April 1990-1991

ITESM "Manager Skills Training".

May-Dec-2000

International Management Development Program Boehringer Ingelheim.

May 2005-Nov 06

Accelleration Growth Executive Program LatAm Teva.

Jan-Dec 2010

IPADE Business School D1 Program,

Oct 2016- Jun 2017

FES Acatlán, Sanitary Rights Specialty (Derecho Sanitario), UNAM

Feb 2022-May 2023

Molecular Biology Master (CEMP)

Feb 2024 – in progress

**Publications**

- "Solid Dosage Form Product transfer-Practical Case- Risk Assessment Approach" as poster presentation at 2008 PDA annual meeting.

- Article publication "Raw material contamination a case study" Enrique Blanco, Journal of GXP Compliance, Volume 6 number 1, October 2001. Institute of Validation Technology.