PharmEng Technology

Kneat PLATFORM PARTNER Kneat Gx

“Global Leaders in Technical and Engineering Consulting Services for cGMP Manufacturing Facilities, Laboratories & Support Infrastructure”

“Your Experts in cGMP Compliance”

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Spain | France | Germany | Switzerland | Austria | Italy | Belgium | Ireland | Denmark | Brazil | Singapore | Taiwan | Malaysia | Canada | USA | Puerto Rico

Company Overview

Executive Summary

PharmEng Technology is a global ISO certified Pharmaceutical Compliance Consulting Firm with projects around the world providing quality services to the manufacturers of pharmaceutical and health care products for over 26 years.

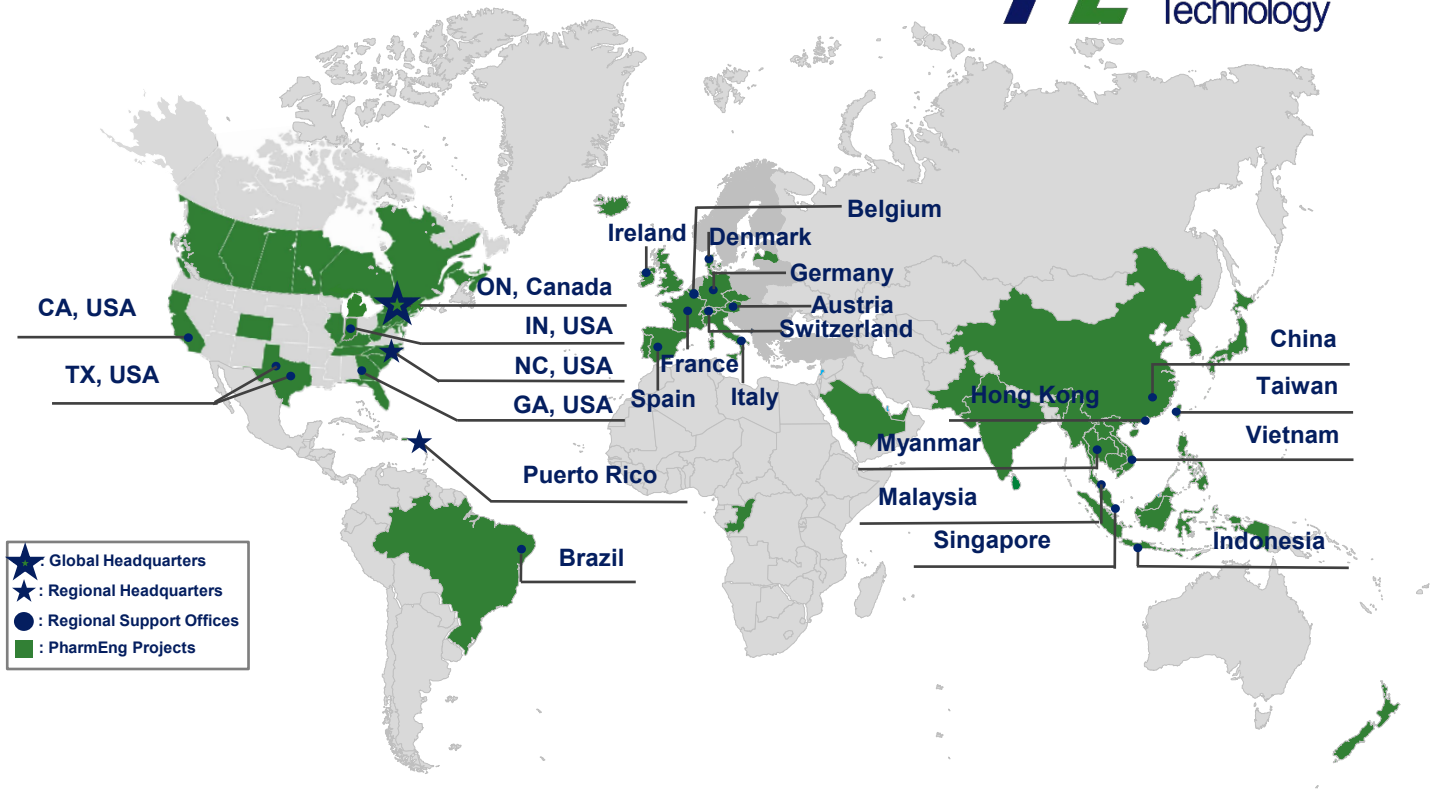
Our 300+ global consultants have expertise in Commissioning & Qualification, Validation, Quality Systems, Regulatory Affairs, Engineering, Medical Devices, Modular Cleanrooms, Toxicology, Thermal Mapping and Training.

PharmEng Technology is a cGMP compliant leader with international offices in Canada, Brazil, Spain, France, Germany, Switzerland, Austria, Italy, Belgium, Singapore, Malaysia, Indonesia, Taiwan, Ireland, Denmark, and USA and maintains strategic partnerships for extended capabilities internationally.

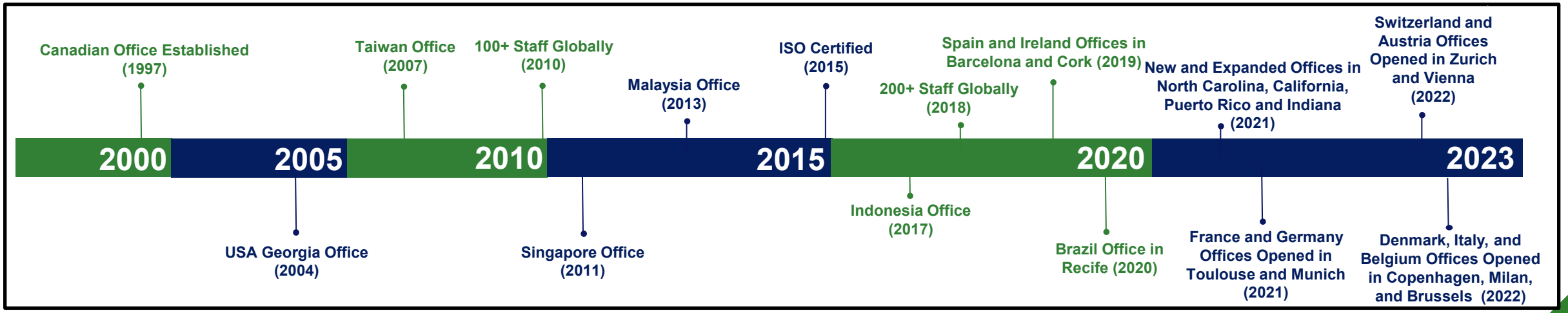
"Global Leaders in Technical and Engineering Consulting Services for cGMP Manufacturing Facilities, Laboratories & Support Infrastructure"

PharmEng at a Glance

- ✓ 26 Years Consulting
- ✓ Pharma and Life Science Focused
- ✓ 300+ Consultants Globally
- ✓ 25 Offices in 20 Countries
- ✓ ISO Certified
- ✓ Diversified Clients and Capabilities
- ✓ Flexible to work multiple ways



Company Milestones



Kneat Partnership

PharmEng Technology

KNEAT
SOLUTIONS

Digital Validation

Kneat PLATFORM PARTNER Kneat Gx

PharmEng Technology is a trusted Kneat Platform Partner. As a Platform Partner we're qualified to provide project- based services and ongoing managed services and support in Kneat Gx for any organization.

We can provide document development and execution, template and property management, process scaling to new sites, new process setup for our customers, and ongoing support to users.

85%

Reduces equipment changeover time by as much as 85%*

*Found in the following independent customer benchmarking study.
Used Kneat for: Commissioning & Qualifi cation, Equipment Validation

50%

Reduces validation life cycle time by over 50%*

*As found by mutiple independent customer benchmarking studies.
Used Kneat for: Commissiong & Qualification

Vision / Mission / Goals

VISION

To bring the most efficient, innovative, and quality solutions to clients to be delivered in a timely and effective manner.

MISSION

To provide unparalleled value to our clients to attain regulatory compliance and maintain a competitive advantage in a dynamic regulatory environment under our "Quality Policy."

GOALS

To assist Pharmaceutical, Biotechnology, Medical Devices and Nutraceutical companies to achieve optimal time-to-market of their pipeline products.

EXECUTIVE LEADERSHIP TEAM

MAY 2023

PRESIDENT & CEO

Alan Kwong

Legal Counsel

Jeffrey Shek

Executive VP & Managing Director, Canada

Alex Della Mora

Executive VP & Managing Director, Americas & Ireland

Bruce Craven

Executive VP, Managing Director, Asia

Kenny Peng

Managing Director, Europe

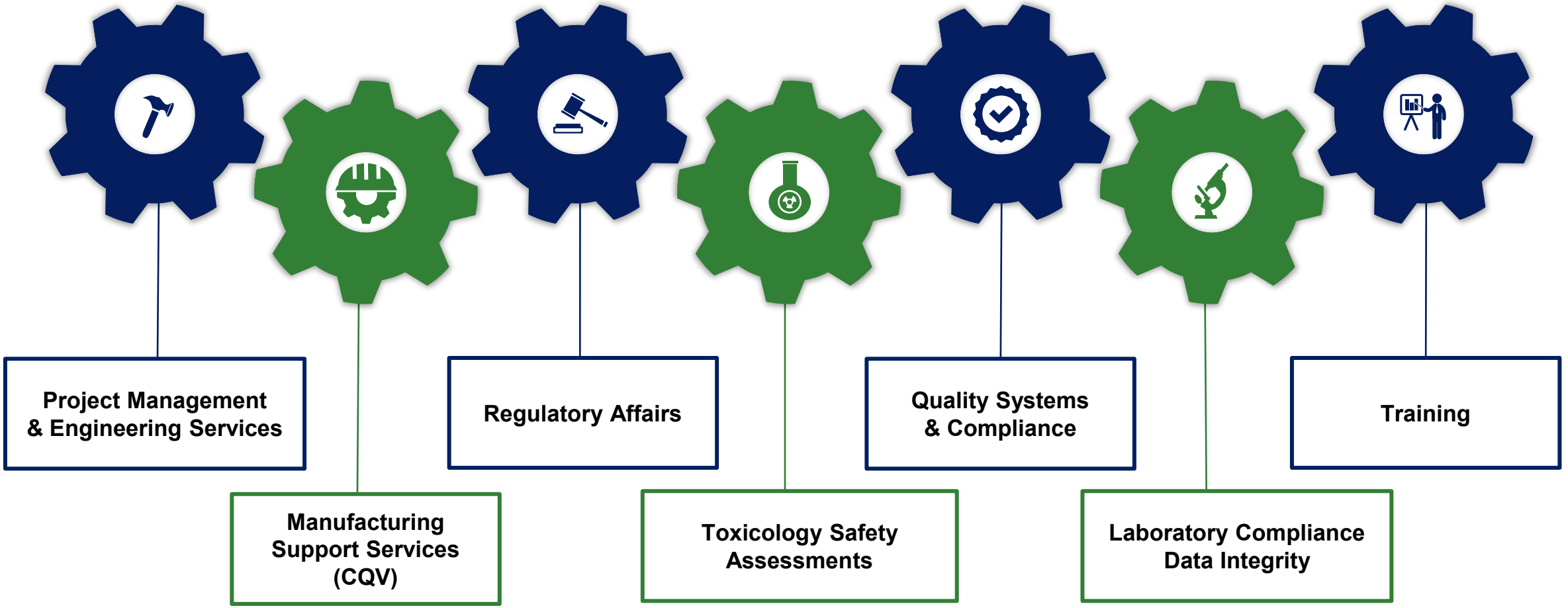
Luiz Grasso

Controller

Alice Wang

Our Services

"We support our clients with rapid, reliable and high-quality consulting services."



Our Services

PharmEng Technology

Biotechnology	Pharmaceuticals	Medical Devices	Cannabis

Project Lifecycle

- Project Management
- Engineering
- Commissioning & Qualification
- Validation

Pre-CD
CD
BD
DD
Build
CQV
Hand Over

Product Lifecycle

Phase 1 & 2 Development
Phase 3 Development
Pre-Market
Post-Market
M&A / Product Transfer

- Regulatory Affairs
- Lab Compliance Services
- Quality Compliance
- Toxicology Assessment

Training

Our Services

"We support our clients with rapid, reliable and high-quality consulting services."

TECHNICAL SERVICES

- GMP/GLP: Engineering, QMS, QA, compliance, validation, supplier audit
- Drug Development: CMC, validation, Scientific Affairs
- Project Management

COMMERCIAL SERVICES

- US, Canada
- China, Taiwan, Hong Kong – South-East Asia
- Europe
- Multi-market regulatory and market strategy

SPECIALTY SERVICES

- International projects: Technology transfer
- Consent decree, serialization
- Professional Training
- International projects: Technology transfer

Our Services (continued)

Project Management & Engineering Services

- Occupational Health & Safety Management
- Facility, Process Planning & Design
- Modelling, Simulation and Scheduling
- Budget & Cost
- Risk Assessment
- Bio-Pharmaceutical Process Engineering
- Environmental Impact Management
- Automation & Process Controls

Manufacturing Support Services

- Commissioning / Qualification / Validation
- Technology Transfer
- Process Validation
- Manufacturing Systems
- Cleaning Validation
- Facility / Utility /Equipment / Instrument Qualification
- Computer System Validation (CSV)
- Packaging
- Data Integrity Assurance

Our Services (continued)

Regulatory Affairs

- Master File Preparation (DMF, SMF, MFA, VMF)
- eCTD / CTD Submission
- Prepare & Submit Post Approval Reports
- Establishment Registration & Renewal
- Product Assessment & Regulation
- Regulatory Strategy & Intelligence
- CMC Preparation
- Pharmacovigilance

Toxicology Safety Assessments

- Toxicology Data & Safety Assessment
- Hazard Identification – Safety Assessments
- Critical Effects – Evaluation of Chemicals & Potential Effects (ADEs, PDEs, OELs)
- Determination of No Observed Adverse Effect Level (NOAEL)
- Uncertainty & Modifying Factors
- Pharmacokinetic Adjustment(s)
- Cleaning Validation Development & Support
- Extractables & Leachables
- Safety Development & Training

Our Services (continued)

Quality Systems & Compliance

- Quality Management Consultation & Training
- Gap & Quality Performance Analysis
- Audit & Inspection Management
- ISO & cGMP Implementation
- Quality System Documentation
- Risk / Crisis & CAPA / Deviation Management
- Environment Monitoring
- ALCOA+ Assessment
- Dealing with Regulatory Organizations (FDA, EMA, AEMPS, etc.)
- Trackable & Traceability Projects for Unforeseen Incidents

Laboratory Compliance

- Method / Assay Validation
- Documentation Audits, Review & Remediation
- Documentation Traceability & Review

Training

- Qualification: Computer / Cleaning / Process / Equipment / Utilities
- RA: Biotechnology, Pharmaceuticals & Medical Devices
- QA: Audit Programs & CAPA
- cGMPs/GLPs: FDA, Health Canada and EU

Toxicology

Toxicology Product Assessment

- Product Characterization
  - API or product Mechanism of Action (MOA)
  - Pharmacokinetics – absorption, distribution, metabolism, excretion (ADME)
- Disease or Ailment Etiology
- Summary of Pre-Clinical & Clinical Trials (if available)
- Summary of Personal Protective Equipment (PPE) for worker safety
- Determination of Manufacturing Product vs. Single Use Technology (SUT)
- Risk Assessment of Product, Health-Based Exposure Limit (HBEL) – Categorization of Overall Toxicity and Permitted Daily Exposure (OEL, µg of API/day) (Data Permitting)
- Safety Training Provided Per Request
- Regulatory & Governance Documents Guidance

Extractables and Leachables

- Evaluation of potential of E&L across manufacturing process by a board-certified toxicologist (DABT)
- Provide assessment of materials & contact chemicals that will not elicit E&L along with list of materials & contact chemicals in which production of E&L is unknown & requires further investigation
- Document all findings via a report & table/spreadsheet
- Zipped file of all references uses in evaluation

Workers Compensation Expert Consulting

- Verbal preliminary case review
- Written evaluation with conclusions supported by weight of evidence
- Impairment determination based on quantitative (amount) data from blood samples
- Zipped file of all references used

Cleaning Validation

- Aligning cleaning validation with toxicological evaluation to meet regulatory expectations
- Implementing results in compliance, and patient safety.
- Modernize cleaning programs focus on patient safety and must include health-based exposure limits (HBEL)
- Customized solution for your CV Master Plan
  - Cleaning Process Design & Development
  - Cleaning Process Performance Qualification
  - Cleaning Process Verification
- Author/revise CV SOPs
- Evaluate toxicity of biopharmaceutics, therapeutic proteins, chemicals, and active pharmaceutical ingredients
  - Determine No Observed Adverse Effect Level (NOAEL)
  - Calculate Permitted Daily Exposure (PDE)

Case Studies

QUALITY COMPLIANCE

Pfizer Michigan

Client: Pfizer USA – Michigan

CQV & Automation

Project Type: Biologic, Vaccine & Gene Therapy

Responsibilities:

- ✓ Automation & Verification Leads
  - ✓ Automation Controls
  - ✓ Aseptic Environment
  - ✓ Production Line
  - ✓ Formulation, Filling, Freeze Drying
- ✓ System Verification
- ✓ Auditing, Testing & Failure Investigations
- ✓ Equipment Startup & Support
- ✓ Configuration Checks
- ✓ Engineering Documentation

Provided over 35 consultants for on-site solutions to support rapid expansion and rollout of vaccine technology. Delivered SMEs in automation controls and aseptic environments, verification engineers & automation engineers. Assisted in verification of automation controls, troubleshooting, configuration, and updating documentation

PharmEng Technology

CQV & AUTOMATION

Pfizer Michigan

Client: Pfizer USA – Michigan

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Rocky Mount, USA

SERVICES

Process Engineering Support and Compliance Review

SCOPE OF WORK

- Author and execute product study protocols
- Follow-up with partner functions (e.g. analytical testing labs, operations, validation) to ensure on-time completion of deliverables. Per guidance from Tech Services establish process parameters, timers, run rates, material flow, etc. as needed
- Assisting in documenting changes/updates to manufacturing processes and working with manufacturing, engineering and validation to implement those changes
- Supporting as a core team member responsible for coordinating and identifying Regulatory and Compliance Remediation activity plans related to product transfer

Rocky Mount, USA

SERVICES

Technical Project Lead

SCOPE OF WORK

- **Support the technology transfer process team on activities related to successfully transferring current marketed drug product to a new external supplier manufacturing sites**
- **Serve as technical lead for gathering product knowledge, collating into easily analyzed formats, generating visual outputs of data and working with other project workstreams on requested deliverables**
- **Assist with generating knowledge transfer documents, technology transfer plans and other transfer related documents between sending / receiving sites**
- **Provide first level review of technical documents generated by receiving site and coordinate internal technical review of sending site / project SMEs**
- **Participate/lead cross-functional team meetings between sending and receiving sites. Generation of notes, output from meetings**
- **Support administrative activities for the workstream such as action/issue item tracking, generation of meeting minutes, coordination of focused working sessions between sending and receiving sites and follow up on actions**
- **Responsible for participating in schedule development and providing monthly status updates to master scheduler**
- **Interact with engineering, regulatory and laboratory workstreams**

Sanford, USA

SERVICES

- *Drug product Gap Assessments*
- *Drug Substance Gap Assessments*
- *Overseeing qualification efforts, change controls, program & process improvements in addition to day to day support*
- *Piping Engineering support*
- *Data integrity support*
- *Change Control support*
- *Process Engineering support*

SCOPE OF WORK

- **Performing technical review for Operations**
- **Performing technical review of regulatory documentation**
- **Performing technical review of SOP and MBRs**
- **Provide technical support for the operations group**

Madrid, Spain
Granada, Spain

SERVICES

Project Management & Engineering Services

SCOPE OF WORK

- **Building Utility Systems Validation**
- **Re-qualification Reports of Nitrogen, Compressed Air, WFI, Purified Water and Clean Steam**
- **Equipment Qualification**
- **Filling Lines Qualification**
- **Change Management**

Madrid, Spain
Granada, Spain

SERVICES

Quality Systems & Compliance

SCOPE OF WORK

- **Internal Audit: Review of Annual Product Quality Review, Quality Records, Change Controls, Investigation Management, Product Approval, Trainings, etc.**
- **Consulting focused on AEMPS, EMA and FDA Regulations**
- **Supporting as a team member responsible for coordinating and identifying Regulatory and Compliance Remediation activity plans related to product transfer**

Madrid, Spain
Granada, Spain

SERVICES

Support in the Introduction and Production of mRNA Vaccines (COVID-19 variants, Flu, RSV)

SCOPE OF WORK

- **Tech Transfer Master Plan**
- **Validation Master Plan**
- **Validation Plans**
- **Process Description**
- **Cleaning Validation Plans, Protocols & Reports**
- **Cleaning Verification Plans, Protocols & Reports**

Madrid, Spain
Granada, Spain

SERVICES

Support in the Introduction and Production of mRNA Vaccines (COVID-19 variants, Flu, RSV)

SCOPE OF WORK

- **mRNA-1273 new vial fill qualification, new vials size qualification**
- **Media fill audit**
- **PPQ Protocols & Reports**
- **Inspected executed PPQ Protocols**
- **Stability Protocols**

Madrid, Spain
Granada, Spain

SERVICES

Support in the Introduction and Production of mRNA Vaccines (COVID-19 variants, Flu, RSV)

SCOPE OF WORK

- **In-Process Hold Time Protocol & Reports**
- **Buffer Hold Time Protocol & Report**
- **Continued Process Verification (CPV) Plan, Protocol & Reports**
- **Creation of SOPs**
- **Gap and Risk Assessments (GARAMP), complains and investigations**

Madrid, Spain
Granada, Spain

SERVICES

Support in the Introduction and Production of mRNA Vaccines (COVID-19 variants, Flu, RSV)

SCOPE OF WORK

- **Assisting in documenting changes/updates and working to implement those changes**
- **Participate/lead cross-functional team meetings between sending and receiving sites and follow up on actions**
- **Project Management for COVID-19 variants qualification**

Madrid, Spain
Granada, Spain

SERVICES

Training

SCOPE OF WORK

- **Good Documentation Practices (GDP)**
- **Visual Inspection focused on FDA, EMA, JAPAN Regulations**
- **Data Integrity, ALCOA assessment**
- **Nitrogen and Compressed Air**
- **Annex I of the EudraLex - Volume 4 - Manufacture Sterile Medicinal Products**

SANOFI

North America / Europe / Asia

SERVICES

PharmEng has provided the cGMP, engineering, validation, and design expertise to ensure that Sanofi facilities met regulatory requirements.

- **Provided validation services & cGMP expertise new and renovated vaccine production and supporting facilities**
- **Provided expertise on vaccine production equipment validation (Includes bioreactors, fermenters, clean-in-place skids, column chromatography skids, and others)**
- **Completed a Cleaning Validation Project for a bin blending suite equipment**

SCOPE OF WORK

- **Computer Validation (New & Legacy Equipment)**
- **Equipment Validation**
- **Building Utility Systems Validation**
- **Warehouse Temperature Mapping**
- **Laboratory Instrument Validation**
- **Cleaning Validation**
- **Process and Cleaning Validation**
- **FDA PAI Audit**

End to End Project Lifecycle

Sanofi Pasteur - Toronto

PharmEng has been consistently delivering high quality consulting services to Sanofi Toronto for

26 Years

Responsibilities:

- ✓ Equipment Validation
- ✓ Building Utility Systems Validation
- ✓ Computer Validation (New & Legacy Equipment)
- ✓ Warehouse Temperature Mapping
- ✓ Laboratory Instrument Validation
- ✓ Cleaning Validation
- ✓ FDA PAI Audit

PharmEng has provided cGMP, engineering, validation, and design expertise to Sanofi Toronto's state-of-the-art facilities for 26 years.

There are presently 65 PharmEng employees on site daily.

Commissioning, Qualification, Validation (CQV)

Synopsis of Multiple Pos for Large Projects

Client: Sanofi Pasteur

Location: Holly Springs, USA

Project Type: cGMP / Engineering / Design / Validation / Regulatory Affairs

Pricing Model: Time and Materials

Responsibilities:

- ✓ Computer Validation
- ✓ Equipment Validation
- ✓ Building Utility Systems Validation
- ✓ Warehouse Temperature Mapping
- ✓ Laboratory Instrument Validation
- ✓ Process and Cleaning Validation

Provided validation services & cGMP expertise new and renovated vaccine production and supporting facilities. Contributed expertise on vaccine production equipment validation (includes bioreactors, fermenters, clean-in-place skids, column chromatography skids, and other). Completed a Cleaning Validation Project for a bin blending suite equipment.

CQV & Automation

Sanofi USA: Swiftwater and Framingham

Swiftwater, PA

Framingham, MA

Responsibilities:

Swiftwater, PA

- ✓ Computer System Validation
- ✓ Equipment and Instrument Validation
- ✓ Building Utility Systems Validation
- ✓ Warehouse Temperature Mapping

Framingham, MA

- ✓ Computer System Validation
- ✓ Manufacturing Automation System Validation
- ✓ Data Integrity
- ✓ Auditing

Provided validation services & cGMP expertise new and renovated vaccine production and supporting facilities. Contributed expertise on vaccine production equipment validation (includes bioreactors, fermenters, clean-in-place skids, column chromatography skids, and other). Validation of MES and DCS. Auditing for UAR.

NOVARTIS

Colorado, USA

Novartis Gene Therapies

SERVICES

Process Engineering support for the Computerized Maintenance Management System (CMMS)

SCOPE OF WORK

- **Development of equipment and maintenance data**
- **Loading of data into CMMS**
- **Review and approval of CMMS data**
- **Support of spare parts identification**
- **Development of preventative maintenance plans**

NOVARTIS

Colorado, USA

Novartis Gene Therapies

SERVICES

MS&T Support (MS&T deliverables support including protocol generation and execution, risk assessments and summary reports)

SCOPE OF WORK

- **PPQ**
- **Comparability Studies**
- **Technology Transfer**
- **Cleaning Validation and related topics**

Eurofarma

Itapevi, Brazil

SERVICES

Quality Systems & Compliance

SCOPE OF WORK

- **Internal Audit**
- **Supplier Audits (China, Mongolia, South Korea, Spain, France, Taiwan, The Netherlands, etc.)**
- **Quality Compliance Assessment**

Design Engineering to CQV / Design-Build

Mycenax Cell Culture Facility

Client: Mycenax Biotech

Location: Jhunan, Taiwan

Project Type: Biopharmaceutical / Interior Fit-Out

Pricing Model: Fixed Price

Responsibilities:

- ✓ Architectural Design
- ✓ Cleanroom and HVAC
- ✓ Procurement
- ✓ Construction Support
- ✓ Commissioning
- ✓ Qualification
- ✓ Process Validation
- ✓ Electrical Distribution
- ✓ Low Voltage / Extra Low Voltage
- ✓ Fire Protection System

The production line 3 of Mycenax Biotech in the current clean room P301 located on 1/F of No 6, Kedung 3 Road, is mainly planned to use a 50L fermenter for the upstream microbial fermentation process. An additional 200L microbial fermenter will be purchased, and room planning, and process flow will be adjusted to fulfil the requirement of the expansion of the production line's three-microbe upstream capacity. Simultaneously carry out downstream room expansion and W302 function modification.

Laboratory Compliance

Project Empower

Client: FujiFilm Diosynth

Location: RTP, USA

Project Type: Biologic, Vaccine & New Drug

Pricing Model: Time and Materials

Responsibilities:

- ✓ Modular IOQ Development for HPLC/LACe System
- ✓ Accommodate over Fifty Units
- ✓ Qualification
- ✓ IOQ Summary Reports
- ✓ Change Management Support

This global upgrade project involved the migration of multiple Empower linked lab equipment components to a new lab facility. Qualification services were necessary to facilitate the relocation of a number HPLC units equipped with LACe acquisition servers. Site representatives operated closely with a cross functional client team composed of Quality Control, Lab Automation, Lab Engineering and MT&S.

Multi-Stage Global Project

Multinational Medical Device Company

Client: ALCON

Locations:

Canada, USA, Malaysia, Indonesia

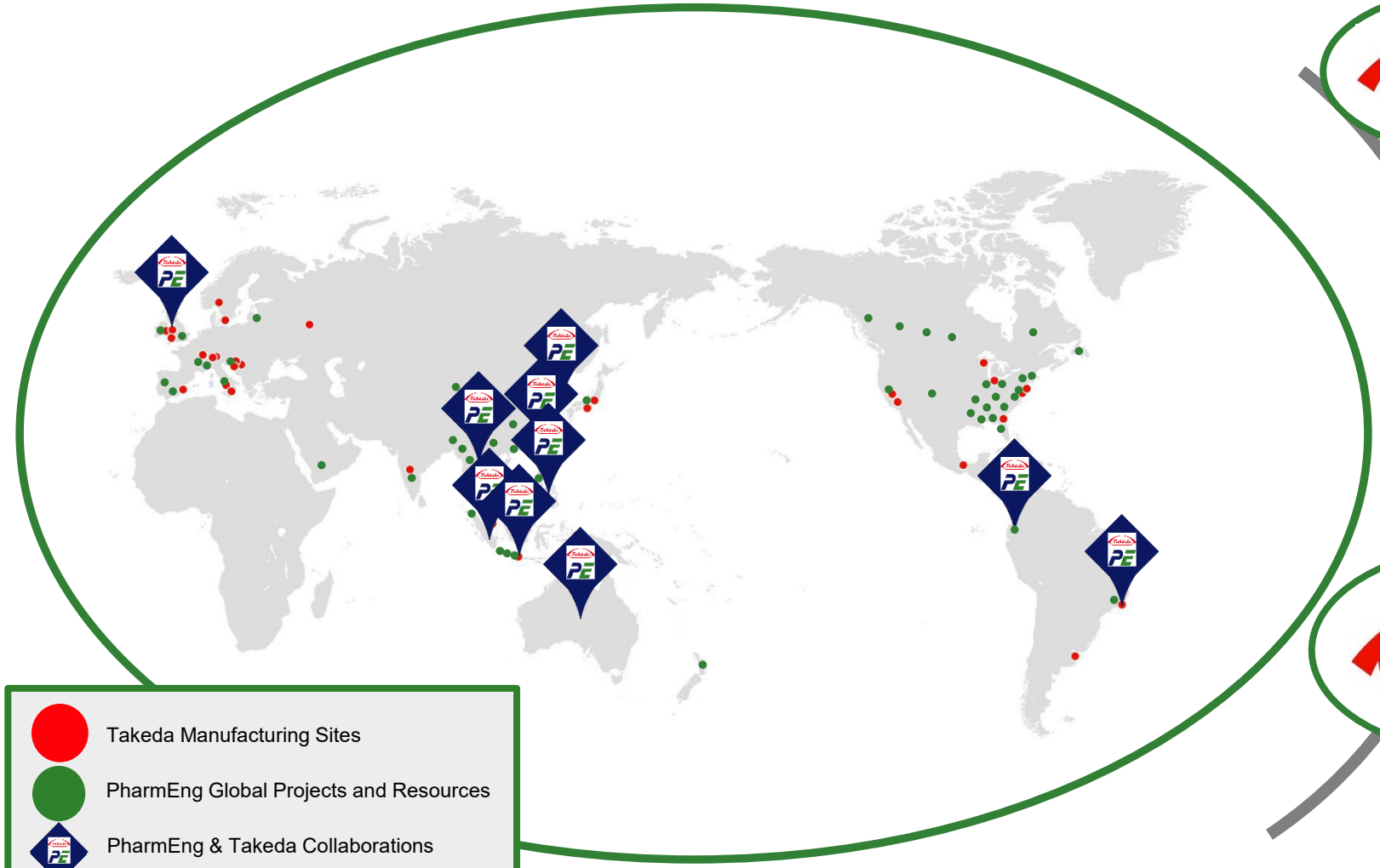
Responsibilities:

- ✓ Quality Systems Gap Remediation
- ✓ Quality Assurance
  - ✓ ISO 13485 Quality System
  - ✓ SOPs Development
  - ✓ Annual Product Review (CPAT)
  - ✓ Product Quality Management (PQM)
- ✓ Technology Transfer & Start Up
- ✓ Facility & Utilities Qualification
- ✓ Validation

Managed Project deliverables and success. Installed 6 manufacturing/packaging lines.

Validated entirety of Process and Equipment.

Projects



Takeda Manufacturing Sites

PharmEng Global Projects and Resources

PharmEng & Takeda Collaborations

Takeda United Kingdom

Global CMC Remediation Project in:

- Philippines
- Singapore
- Thailand
- Taiwan
- Indonesia

Takeda Indonesia

Halal Compliance

Global CMC Remediation Project

Takeda United Kingdom

Chemistry, Manufacturing & Control CMC Compliance

Sub-Contracted by Takeda United Kingdom for:

- ✓ CMC Compliance Analysis
- ✓ Remediation
- ✓ GAP Analysis

5 Sites Inspected & Remediated

Countries:

- ***Taiwan***
- ***Thailand***
- ***Philippines***
- ***Indonesia***
- ***Singapore***

SERVICES

Halal Compliance

Indonesia:

RDTX Tower 10th Floor, Jl. Prof. Dr. Satrio Kav. E-IV No.6,

SCOPE OF WORK

- **Halal readiness preparation services**
- **Site has been Halal-approved**
- **Project Leader: Dody Tanusubandi**

SERVICES

Validation Support Services

Singapore (formerly Baxter):

Woodlands Industrial Park D St 2, Singapore 737778

SCOPE OF WORK

- **To be agreed**
- **Project starting in a few weeks**

SERVICES

Qualification Services

Calfornia (formerly Baxter)

SCOPE OF WORK

- **Temperature Mapping Services**

CQV

Takeda Indonesia

Client: Takeda Indonesia

Location: Jakarta, Indonesia

Project Type: Cleaning Validation

Responsibilities:

- Validation Plan
- Cleaning validation procedures
- Analytical detergent procedures
- Equipment cleaning SOPs
- Cleaning development protocol and reports
- Cleaning validation protocol and reports

Provided Cleaning Validation Support

Bioconjugates

COMPANY	COUNTRIES	BIOCONJUGATE	PROJECT DESCRIPTION
ROVI	Spain (2021-2023)	mRNA-LNP Vaccines (COVID-19, Flu, RSV)	• Stability studies. • Tech Transfer from Moderna (Norwood, USA) and Lonza (Visp, CH). • Process and Equipment Qualification & Validation – CPV. • Audits.

Bioconjugates

- In PharmEng Technology we have extensive experience with both ends of the spectrum (biological and chemical manufacturing processes)
- Here we show a few examples in which we have worked globally involving those processes:

COMPANY	COUNTRIES	MOLECULE TYPE	PROJECT DESCRIPTION
Pfizer	Canada, USA, Asia (Since 2005)	Chemical/Biologic	• Qualification & Validation of new Facility and Lines. • CMC regulatory compliance.
FUJIFILM Diosynth biotechnologies	USA (Since 2018)	Chemical/Biologic	• Toxicology assessment. • Facility expansion boosting Cell Culture manufacturing capacity by 25% and Microbial manufacturing capacity by 50%. • Full IOPQ development and execution for all process equipment. • Qualification Service in QC Equipment.
Alvogen	Taiwan, Iceland, Malaysia (Since 2014)	Chemical/Biologic/ Cytotoxic	• FDA pre-Audit preparation and QA remediation. • Facility status quo Assessment. • CQ support. • Regulatory Affairs.
Clarivate™	Asia (Since 2015)	Chemical/Biologic/ Medical Device	• Regulatory Intelligence and Writing
pharmacore group	Taiwan (2019)	Chemical/Biologic/ Cytotoxic	• GMP Audit and advisory for planned USA launch

Cell Gene Therapies

COMPANY	COUNTRIES	PROJECT DESCRIPTION
NOVARTIS	Canada, USA, UK, Ireland, Singapore, Malaysia, Indonesia (Since 2007)	• Long-term ongoing support in all quality, validation, and manufacturing aspects. • Due diligence support for the Company's oversea partner acquisition.
Pfizer	USA (Since 2020)	• Resources provided: Process engineers, Project engineer, Validation Remediation Work, Technical Writers and Investigators
Encoded THERAPEUTICS	USA (Since 2021)	• Project Management: Manufacturing & Technology Transfer
FERRING PHARMACEUTICALS	Denmark (2019)	• Feasibility study and conceptual brief for a biopharm facility. • Process flow layout design and working with the architect on facility layout.
ARK Therapeutic Products	Finland (2017)	• Optimising of the production process. • Identification of suitable suppliers for a process.

Swiss Medic

- We have been working in ROVI with the Swiss agency at the time to register the Moderna vaccines around Europe.
- This has been performed for 2 years (2021-2023)

Strengths

1) Experienced : *Highly qualified, dedicated, and rapidly growing professional team*

Professional…

Our **300+ consultants** are specialized in pharmaceutical, biotechnology and engineering industries. We are critically selective of our resources and maintain optimally experienced staff from entry level to SMEs.

Diversified…

Our company is a multinational company with staff providing services globally for **clients small to large**. Our international presence ensures we maintain our knowledge of regulatory practices and on the “cutting edge” of emerging trends around the globe.

Leadership…

Our leadership team has multiple years of industry experience which allows us to be extremely agile and responsive to our clients. PharmEng has maintained an impeccable reputation **since 1997**, and will continue to do so.

Strengths (continued)

2) Efficient: *Client focused service that delivers quality results on time and within budget*

Testimonials…

"Due to your efforts and support for the GTx DS and DP verification assessment and gap remediation efforts, consistency, documentation corrections and compliance gaps have been identified. The thoroughness of your assessments/reviews has allowed GTx to determine remediation actions and timelines so that there is no impact.

You demonstrated the value of excellence in working as a Sanford team to ensure compliance which will lead to successful PAI and general audits in the upcoming years. There was a lot of time and effort put into these assessments and we thank you for your expertise and contributions."
- Pfizer

"I am very delighted to announce that we have completed the SoftMax validation project in QC Immunochemistry at Sanofi Pasteur . During this project, a total of 5 SoftMax templates were validated and implemented on time (before 31May2016).

This project has a big impact on our operations in Quality Control as it is directly related to the improvement of quality and efficiency for our department.
I am sending this email to personally thank PharmEng Technology for their unaccountable contribution in completion of this project."
- Sanofi Pasteur (Nirav Patel - QC Immunochemistry Manager)

Our Clients

Proven: *Professionals in various multi-million projects every year*

SANOFI · Pfizer · Lilly · Johnson & Johnson · Roche · MERCK · abbvie

gsk · moderna · BAYER · Takeda · Boehringer Ingelheim · novo nordisk® · TEVA PHARMACEUTICAL INDUSTRIES LTD.

FUJIFILM Diosynth biotechnologies · NOVARTIS · SANDOZ A Novartis Division · Daiichi-Sankyo · Baxter · ROVI · APOTEX

Biogen · ESTÉE LAUDER · REGENERON · SUMMIT Biosciences Inc. · SAMSUNG BIOLOGICS · Seqirus A CSL COMPANY · PRO.MED.CS Praha a.s. · VALEANT Pharmaceuticals International · Skelton Truck Lines · AIN MEDICARE · Henlius · 天普藥業 TECHPOOL · DKSH

Hospira · CELLTRION · Eurofarma · Medytox · B|BRAUN · Encoded THERAPEUTICS · JLL Japan Lifeline · fidia farmaceutici · CKD OTTO Pharma · CP Guojian Pharm 中信国健 · ccm CCM PHARMACEUTICALS DIVISION

台灣神隆股份有限公司 ScinoPharm Taiwan, Ltd. · CanSinoBIO · SEQENS · MILANI · AGC Biologics · United Therapeutics CORPORATION · kimia farma · PharmaCore 博騰生技股份有限公司 · EVER PHARMA · RESILIENCE · biogen idec

Otsuka · Sinphar · Canadian Blood Services it's in you to give · novugen · SickKids · U-Liang 優良 · AMGEN · FRESENIUS KABI · Alcon · TYCHAN · LINKHEALTHCARE · YENCHEN · R4 · BIOSENSORS INTERNATIONAL

Certifications

ISO 9001:2015 - National Ministry Supplier Development Council

CERTIFICATE OF REGISTRATION

This is to certify that

PharmEng Technology Inc.

23 Lesmill Road, Suite 410 Toronto, Ontario, M3B 3P6, Canada

operates a

Quality Management System

which complies with the requirements of

ISO 9001:2015

for the following scope of certification

Office supporting function and services (HR, Accounting and IT) in providing resources for consulting to the Life Science Industry in North America.

Certificate No.:	CERT-0118765	Original Certification Date:	May 14, 2013
File No.:	1623134	Certification Effective Date:	May 12, 2021
Issue Date:	May 4, 2021	Certificate Expiry Date:	May 11, 2024

Frank Camasta
Global Head of Technical Services
SAI Global Assurance

ISO 9001

SAI GLOBAL

ASQ CERTIFIED Quality Auditor

ASQ CERTIFIED Medical Device Auditor

ASQ CERTIFIED Six Sigma Green Belt

ASQ CERTIFIED Pharmaceutical GMP Professional

ASQ CERTIFIED Manager of Quality/ Organizational Excellence

Trained Certified Engineers

CIA Certified Internal Auditor

Professional Engineers Ontario

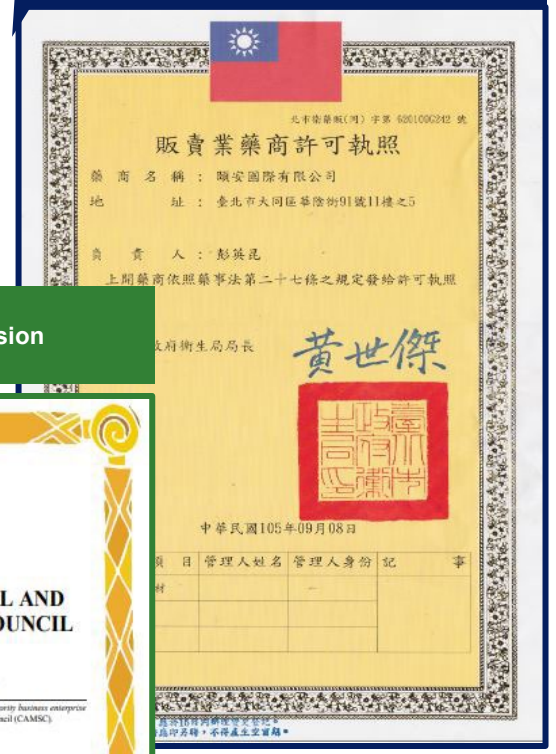
Project Management Institute PMP® Certified

Certifications (continued)

Certificate of Conformity Good Distribution Practice for Medical Device - (Malaysia)

Medical Device Establishment License (Malaysia)

Pharmaceutical Wholesaler License (Taiwan)



SOCOTEC International Certification Good Distribution Practice for Medical Devices - (Singapore)

Diversity and Inclusion

PE Resources / Projects in Europe and South America

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