ipg
ice pharma group

Corporate Presentation

"We bring together our experience and knowledge to build project strategies that span multiple functions across the pharmaceutical journey to bring a product to market...

"We design & develop solutions for your business.

We also provide pharmaceutical products and complimentary services.

ABOUT US

We are here to understand your business and growth objectives, and tailor our plans to fit your specific needs.

"Nothing we do is theory"

This presentation will demonstrate how we have assisted our clients and met their businesses needs. It will also share with you our experience of helping our clients achieve their aspirations through a series of case studies.

Nothing we do is theory, everything we do for you,
we also do for ourselves.

WHAT WE DO

IPG Pharma is a generic pharmaceutical company with its own Marketing Authorisations (MAs).

IPG was founded in the UK in 1999 to source API's and intermediates. The company achieved early success in introducing new Indian and Chinese manufacturers to the generics sector. Moving up the value chain.

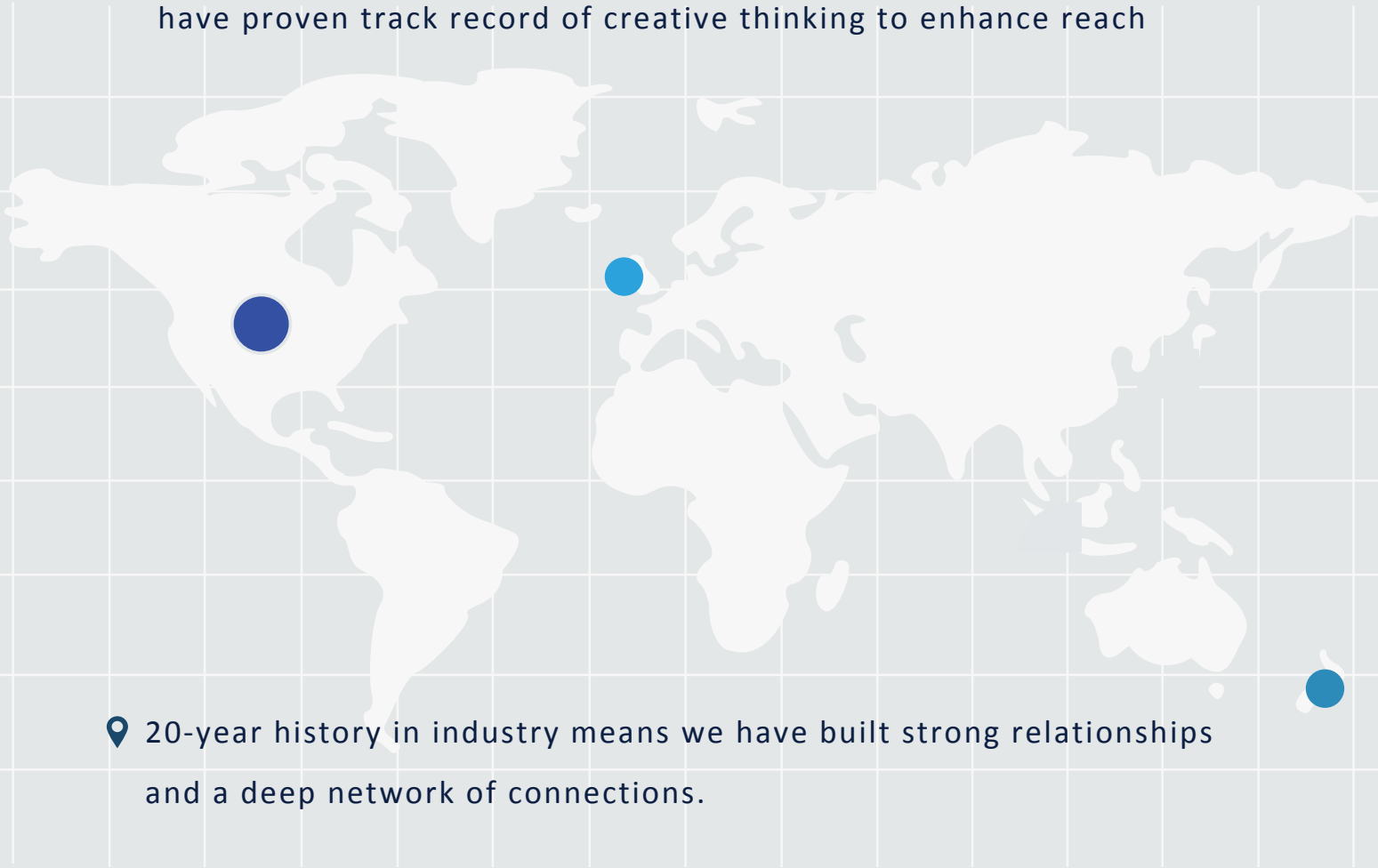
IPG holds and has held MHRA approvals over the past 20 years for Manufacturing and Importation Authorisation (MIA) and Wholesale Distribution Authorisation (WDA) for import and sales of products in Europe along with GMP and GDP approvals and license to import API's. We have gained significant expertise. Our experienced operational teams manage the supply chain from API through to a final product release.

We specialise in providing pharmaceutical products and services to create tailored pharmaceutical solutions to help our customers get the best out of their business.

GLOBAL REACH

We have offices in the UK, New Zealand and Canada. We operate mainly within the EU, Middle Eastern, and Far Eastern Markets, we have been operating in China since 2005 and in America since 1999.

- We have industry connections in every continent across the globe.
- As the developer and creator of the first buyer and seller meeting place for the purchase and sale of dossiers called Generic Licensing we have proven track record of creative thinking to enhance reach



- 20-year history in industry means we have built strong relationships and a deep network of connections.
- We have a database of tens of thousands of engaged healthcare and pharma industry professionals accessed via our digital channels
- Our next creative platform is currently in the making...

GLOBAL NETWORKS

SALES NETWORK

- INDONESIA for Far East excl China
- CHINA
- CANADA for North America
- NEW ZEALAND for Asia Pacific
- SOUTH AFRICA and up to the Sahara
- UNITED KINGDOM
- EU
- MENA
- SOUTH AMERICA

PRODUCTION & SUPPLIER NETWORK

- CHINA
- INDONESIA
- TAIWAN
- INDIA
- ITALY, SPAIN, UK, PORTUGAL, FINLAND, GREECE, HOLLAND
- USA
- BRAZIL

OUR EXPERTISE

Our expertise is built on over 20 years of industry knowledge and experience. Our core staff bring a wealth of industry know how.

We have worked on a large variety of projects from sourcing novel APIs to getting new workshops GMP approved. We have worked on large complex projects that encompass sourcing licenses, gaining 120 EU marketing authorisations for one client together with commercial supply across 18 EU countries, as well as delivering hundreds of products into developing nations and large-scale supplies of personal protective products across the world. With an extensive network, our reach is global.

Our core capabilities include:

- ❖ Supply chain management
- ❖ Complex projects
- ❖ Regulatory and compliance
- ❖ Sourcing and supply
- ❖ Licensing

We bring together our experience and knowledge to build project strategies that span multiple functions across the pharmaceutical journey to bring a product to market.

Our strategies are built on more than just process and tools.

We come to understand your business and growth objectives, and tailor our plans to fit your specific needs.

FOUNDATIONS OF EXCELLENCE

Quality & Reliability

Quality and reliable service and products are core principles embedded into our company. Our clients and partners can rely on the quality and accuracy of our work.

Deliverables

Part of our mission is to provide effective solutions. We strive to offer products and services where total acquisition costs is a core requirement whether we are taking on a new product to grow a business footprint or secure suppliers that match stated goals.

Experience & Expertise

Our team has decades of experience, knowledge and skills in niche sectors of the industry. No challenge thus far is beyond our capability.

Adaptable

We recognise that our customers and partners have unique needs. Our solutions are not out-of-the-box, we adapt our toolkit of skills to match your needs modifying them along the way as required.

TIMELINE

OUR HISTORY

IPG has built extensive experience through a range of projects and has built a network of highly skilled industry experts in manufacturing generic products, owning licenses and providing support services to multiple pharmaceutical businesses.

MILESTONES

1999 — IPG Founded

IPG was founded by David Kenneth Bilton in 1999 to source APIs.

2003 — China

Started trading finished dose and China operations established

2007 — Licenses

First MA in UK market (Enalapril).
MIA and WDA licenses granted

2009 — Launching

Opened the Canadian Offices. Launched Generic Licensing

2010 — Tech Transfers

China tech transfers started

TIMELINE

2012 — End to End

First Full Service Client

2013 — NHS

First NHS Tender won for 3 molecules

2014 — Global Reach

New Zealand Office Opened.

2017 — Supply Chain

Complex supply chain first project

2018 — Africa

1 st supply TB & PPE products to Africa

2019 — New Business Launch

Launched men’s telehealth program

2020 — PPE Launch

Progressed with PPE into global market place

2022 — Business Expansion

Business expansion and scheduled launch into cosmeceuticals

AN INTRODUCTION TO THE BENEFITS OF PRODUCTS

IPG has become known for tailoring their solutions to client needs.
Most clients come to IPG seeking a specific product or service, after a free initial consultation we develop a programme that helps our client expand their business more effectively using our expertise.

We often hear phrases like...

At IPG, we enjoy a challenge...

We have assisted some of the top global generic companies in securing difficult to source APIs, then managing their supply chains in particular ways to match their needs. We have supplied API for more than 25 patent off date products, finding licenses for clients and then handling the entire pharma operations (bar finance and sales) and sitting as advisors on company boards.

OUR PRODUCT OFFERINGS

What products do we offer?

We offer a range of products including active pharmaceutical ingredients, generic pharmaceutical product dossiers, personal protective equipment, virus testing kits and infectious disease medication finished products.

You can view our most recent product lists via our website www.icepharamgroup.com/products

We also supply RLD and Clinical Supply as well as API's for special compilation and licensed finished products from outside the UK.

DOSSIERS

We market a range of dossiers which are suitable for almost all countries in the world being mainly in EU CTD format as well as dossiers suitable for lesser regulated markets.

Dossiers are often where a client commences their journey with IPG and progresses to our service and solution offerings.
Only some of our dossiers feature on our website at any one time. Therefore, if a product dossier you are searching for is not on our website, please enquire as we may well be able to assist. We also have a dossier sourcing service. We will soon be marketing dossiers, where patents are not yet expired, for clients to prepare for commercial patent off date and some of these will feature full regulatory service as part of EU DCP.

Not actively marketed, IPG can undertake client specific formulation development through to dossier preparation and onto to MA application and then supply. We also provide reference leader drugs and clinical trials supply.

API & INFECTIOUS DISEASES

API

We market a range of APIs which can be seen on our website. We have chosen our partners with great care so that they match our exacting criteria. Our partners have GMP approvals from all the major regulatory bodies. A number of APIs are featured that have future patent expiry dates and some IPG can take through to submission ready dossiers by client request. We also supply small quantities of APIs for specials compounding.

Infectious Diseases

These products along with their support product range have been selling in Africa and other challenged countries via official tenders. We have partnered with a few select companies that are focused in this volatile business area, one of these sits in the approved pharma support group at the WHO. With the supply of generics with significant regulatory approval (SRA) and our PPE catalogue, we are well equipped in this sector.

MARKETING & OUTLICENSING

With our reach around the world, we consider ourselves well placed to undertake assignments to locate, negotiate and close out licensing deals for clients product's in the Pharmaceutical and Healthcare sectors. We have many case studies demonstrating our expertise in multiple sectors, however we cannot discuss client's details.

In 2011 we developed the industries first and largest online platform to connect licensing and distribution partners. We have partnerships and collaborations locally, regionally and internationally.

In the UK we can reach almost all sales outlets and are approved to supply NHS tenders. In a number of other countries we have a similar reach.

We have represented over 252 innovative RX and OTC products that were selected for market attraction in important therapeutic classes including Diabetes, Anti-infective, CNS, Pain, Oncology and Gastrointestinal.

We also use our network to seek for in-licensing arrangements.

If you are searching for a sourcing service then look no further, we operate a highly functional sourcing service that can be tailored to meet your specific needs. If you can't find what you are looking for please get in touch.

OUR SERVICES

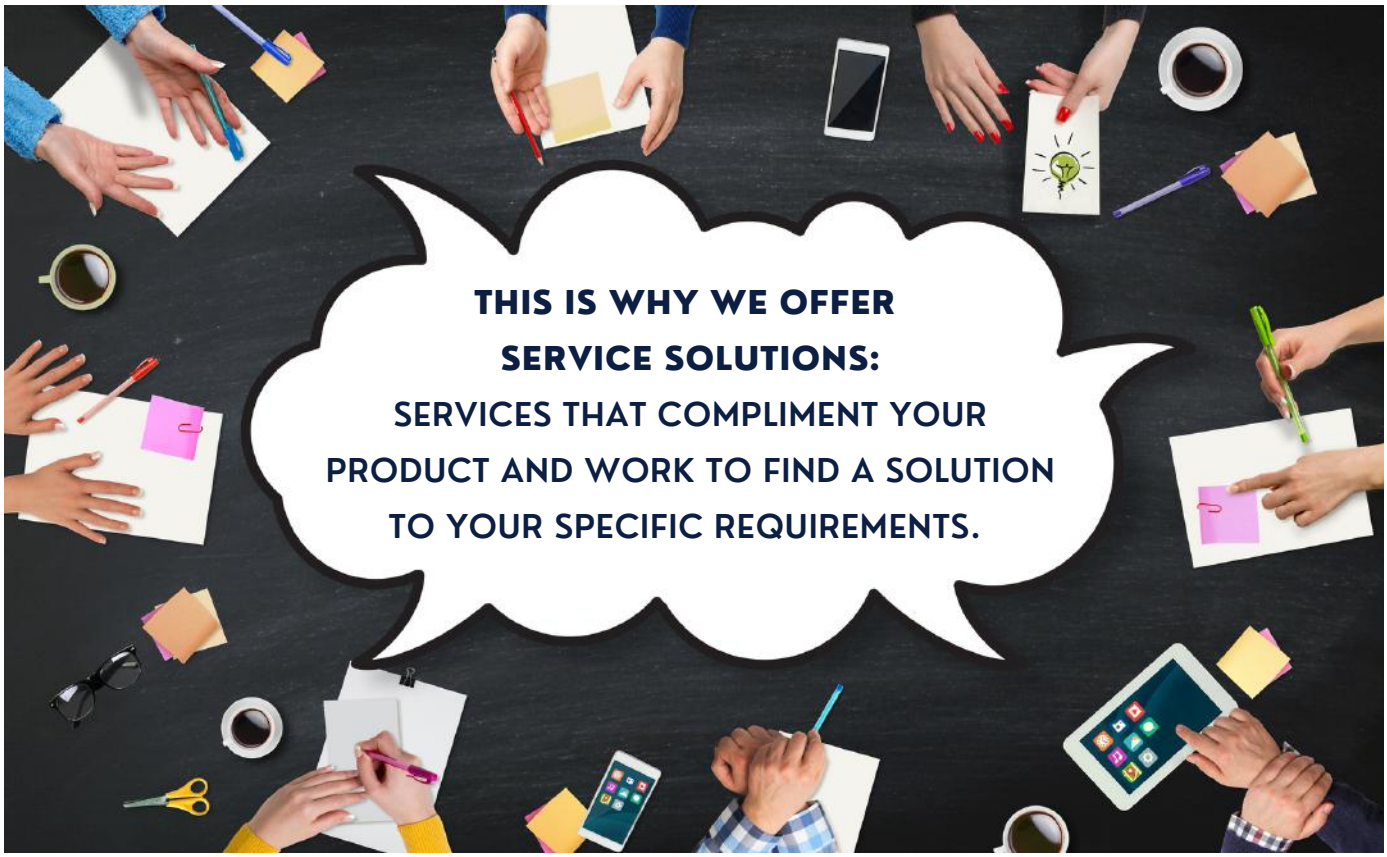
PICK & MIX
YOUR CUSTOM SERICES PACKAGE

- Hospital & Pharmacy Direct delivery (UK)
- Business Development & Marketing Service
- Quality Management
- Regulatory & Compliance Services
- Project Management
- Operations Management
- Supply Chain Management
- Clinical Trial & RLD Supply
- Dossier Sale, License & Supply
- Marketing Authorisations
- Technical Transfers & Template agreements
- Global distribution & logistics
- Product Sourcing
- Dossier GAP Analysis
- API Sourcing
- & Supply
- GMP Facility Approval
- Auditing Services
- ROI Costing

You can explore our service offerings via our website
www.icepharamgroup.com/services

OUR SOLUTIONS

We appreciate that some companies simply wish to buy their chosen product and then go on to their next assignment, however this is not always the case. Clients that have approached us seeking just one product have over time grown their business alongside IPG Service Packages, Solutions, and additional Products.



The service solutions we build for our customers are designed to be uniquely tailored to suit their specific needs.

We have a wealth of knowledge and experience. This is demonstrated within our Case Studies section of this document, where we share real examples of how we have pulled together our product offerings and service offerings to create these bespoke service solutions.

Case Study

SAMPLE CLIENT JOURNEY

FULL-SERVICE CLIENT

We worked with a company that was a one year old start up with private equity funding. Their business model was bringing generic injectable products from vertically integrated facilities in the Far East through to the UK market and then expanding across Europe and the USA.

They ended up with 120 MAs at the end of IPGs tenure (and supply chain operations from five factories in the Far East) released into Europe through to hospitals.

Phased in over 12 months, IPG became responsible for managing the entire Technical and Supply Chain Operations.

IPG services included: supply chain and logistics, regulatory management, PV management, dossier management and storage, QP release to market, quality management, GMP auditing, commercial and integrated project management, SOP implementation, procedures, polices , supplier approval systems and artwork preparation.

Additionally, an IPG Director was appointed as COO to manage and have oversight responsibility of all Operations. We also recruited a client-side project team to work with our IPG team.

Case Study

MEN'S TELEHEALTH CLIENT

A new start up client initially approached us for a pharmaceutical dossier for a single product . Their business model was to provide affordable men's hair loss and well -being products online in the United Kingdom and Ireland.

IPG finalised a deal for two products; a partnership with a UK Pharmacy integrated with General Practitioners and a UK repacking site. We obtained a successful launch in December 2019.

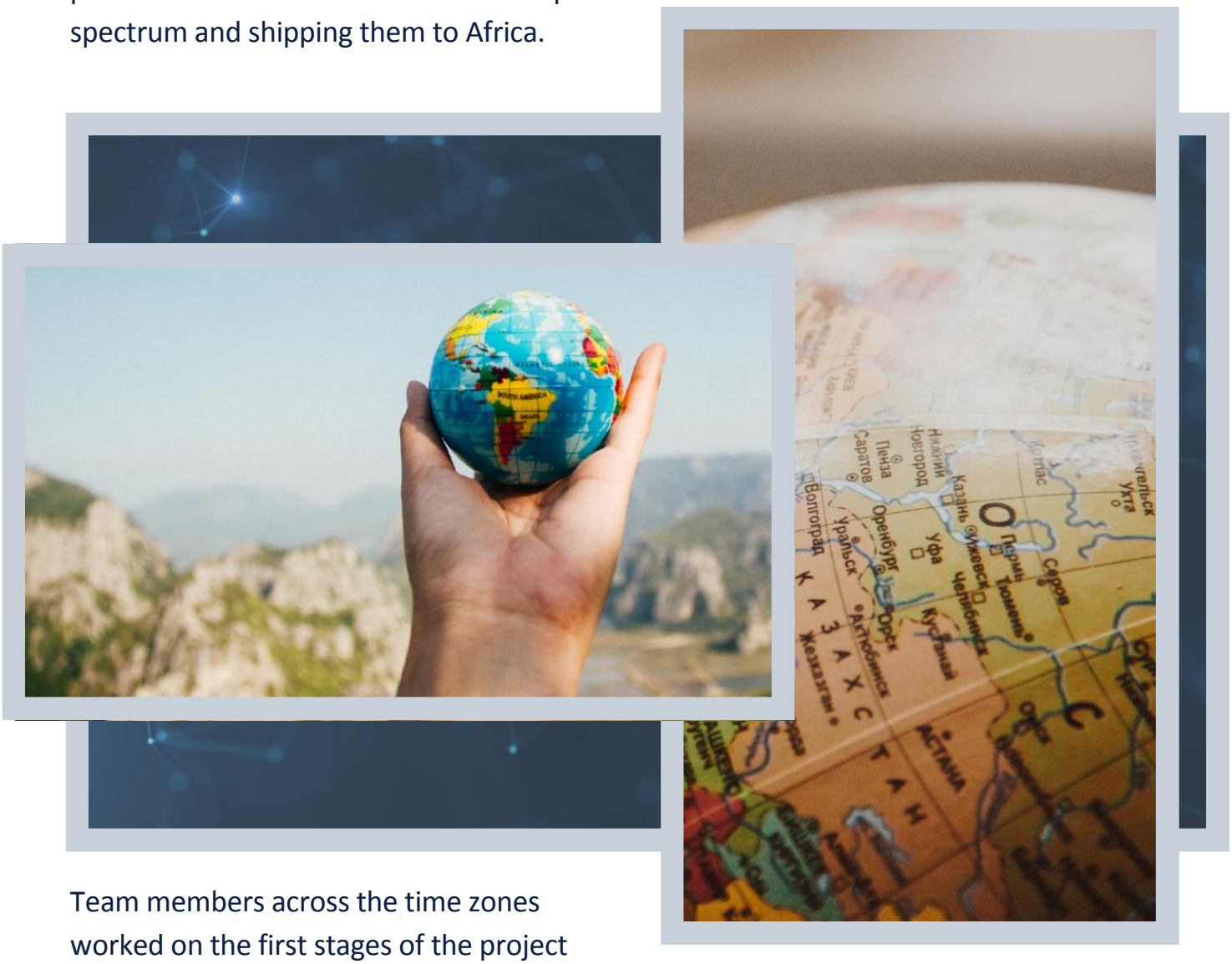
Over the phase of 1 - year IPG became responsible for all Technical, Supply Chain, Regulatory and Project Management.

After 3 years partnered and successful further investment expansion into Europe is underway

GLOBAL MULTI-SOURCE CLIENT

Providing healthcare products into Africa presents a number of challenges and requires a specialised approach by companies who are familiar with business operations across the continent. There are some African markets however, that are moving to a form of tender model, yet even this model requires comprehensive financial risk management planning.

A financial institution approached IPG to work to supply critical items. Once a complex contract with certain assurances was in place our task was the large scale sourcing of 295 products across a wide healthcare and pharma spectrum and shipping them to Africa.



Team members across the time zones worked on the first stages of the project to line up 295 Products, 1,750,514 packs from 6 countries.

As with most new projects, the initial set up is resource heavy and utilizes our full services scope. Additionally, this project involved multiple time zones to manage the freight movements and currency management.

ONCOLOGY CLIENT

A client came to us seeking oncology marketing authorisations for as many EU countries as possible. Over a two-year period, we concluded deals for nine molecules and after running additional registrations the client had MA's in eleven member states.
IPG ran all the regulatory procedures, quality management and supply chain.

In parallel the client was constructing a new facility and IPG were engaged to oversee the engineering validation, quality compliance by locating team members in the facility for three weeks a month for two years.

We successfully obtained EU GMP approval on first inspection with short corrective action plan - from a brown field through technical transfer to first tender supply in just over 4 years.

MARKETING CASE EXAMPLES

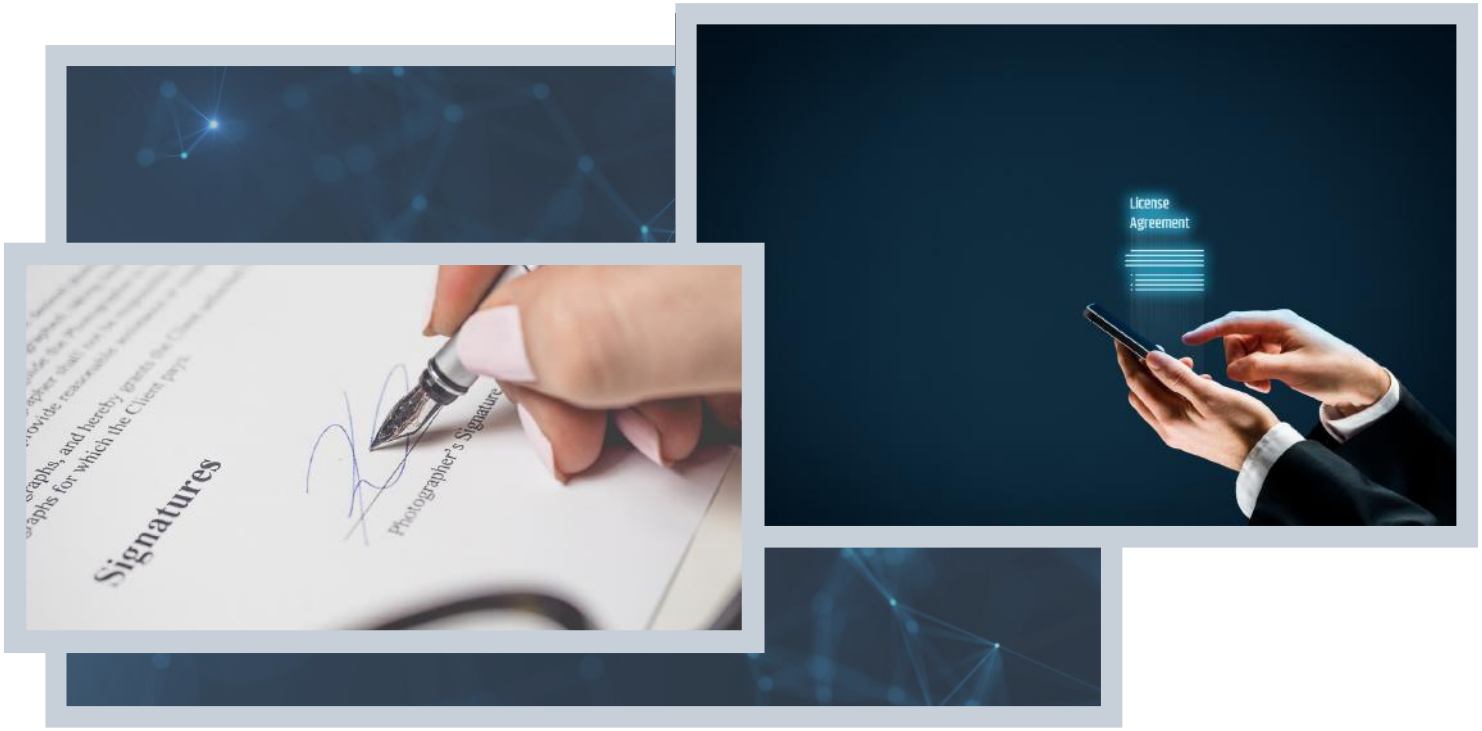
Successful campaigns come in all sorts of shapes and sizes.

When a unique CE marked delivery of medicine for children approached us we seized the challenge to bring the product to the world stage. The product crossed numerous sales channels from direct to consumer, mother and toddler stores, healthcare and general sale routes needing local distributors in multiple countries which we managed under a master collaboration agreement. To bring such products into view, touch and feel were important, so exhibitions and sampling become a vital part of the marketing mix.

We were presented with the opportunity to manage the only CE Marked Cough Syrup product under a global arrangement. This is certainly a very busy competitive market place littered with global brands, so differentiation was required as well as novel sale approaches. In the UK we branded the product and marketed it for children. So far, we have covered the Nordics and continue to pursue growth through our network. A sister product is moving forward with patented rapid pain relief claims and whilst already being made and sold in Indonesia (under licence), in Europe and USA the product requires full regulatory approval before the sales partners can sell.

OUT LICENSING CASE EXAMPLES

A client approached us wanting to expand their global reach firstly into Europe and then beyond. Utilising our extensive global network we were able to present to the client an initial 18 countries as options for expansion, and suggestions of further international opportunities.



Success was achieved by following a series of core steps:

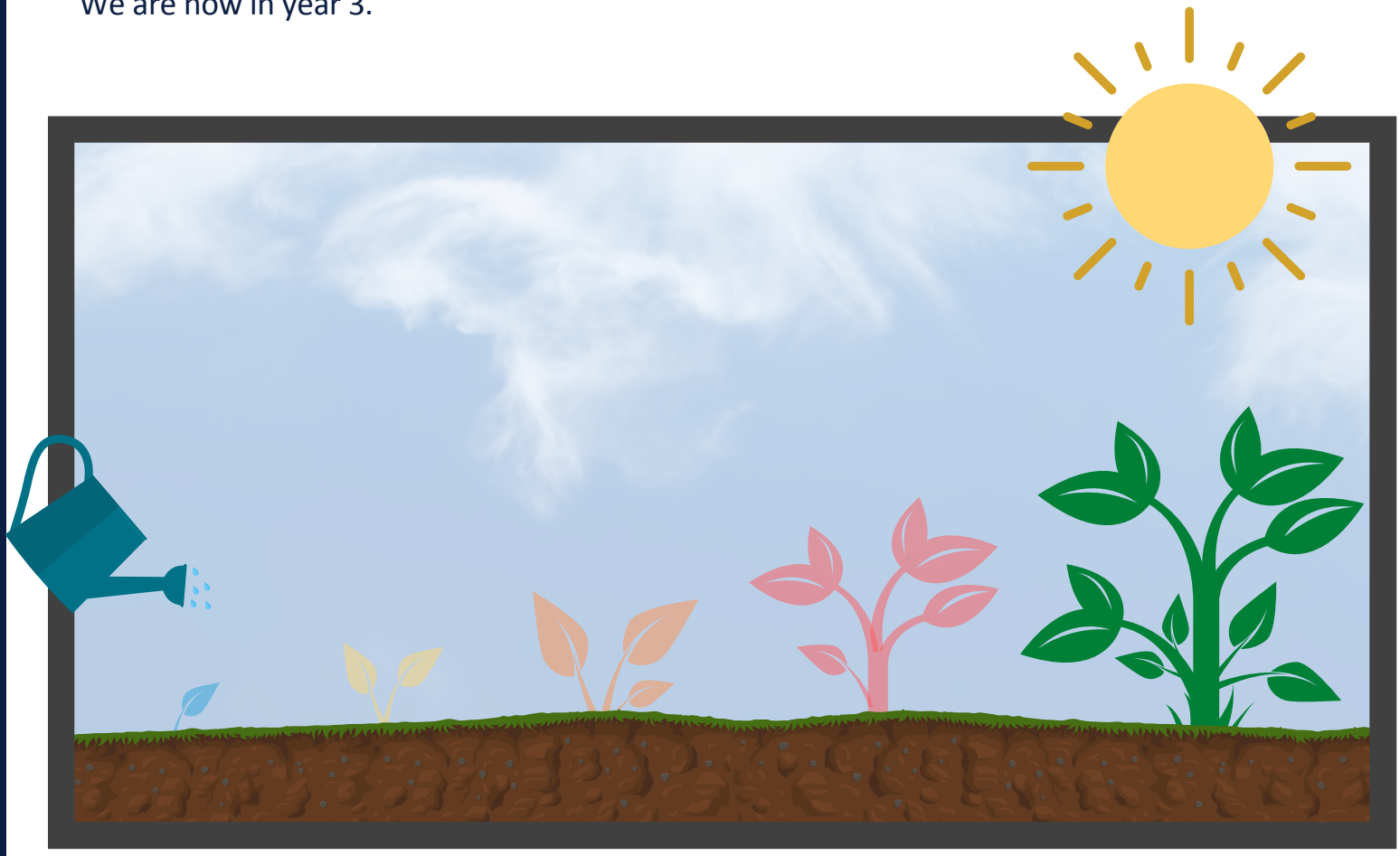
1. Connected with partners in 18 countries to refine each distribution market.
2. Solidified a series of fundamental questions on the partners approach, methods and ability to target this particular therapeutic delivery.
3. Provided partners with a product information package, educational material and other applicable data.
4. Officially confirmed partners interest.
5. Gathered data on projected volumes followed by a COGs proposal, and License & Supply terms.
6. Debated and agreed the regulatory strategies and timetable to market.
7. Took a country-phased approach and supported with regulatory and supply chain management.

Once the product was successfully in each market we passed over all operational, regulatory, supply chain and relationship management back over to the client.

GROWTH WITH THE RIGHT AMOUNT OF NUTRIENTS

Case example of client engaged Jan 2019.

IPG was contracted for product sourcing through all technical operations to supply to market. We are now in year 3.



1. A few products
   Great potential
   Needs watering
2. Five-year plan presented
   New licenses
   Needs plant food
3. Five-year plan presented
   New licenses
   Needs plant food
4. Infrastructure mature
   All aspects rapid growth
   Continue feeding
5. Over 50 products in market
   Looking mature and ready for more branches

You can view our most recent product lists, solutions and services via our website
www.icepharamgroup.com

KEY DEPARTMENTS AND WORK STREAMS MANAGED

Our Key Functions & Explanations

SUPPLY CHAIN

Our supply chain team engage in a series of steps to get your product from manufacturing to your customer.

These steps include moving and transforming raw materials into finished products, transporting those products, and distributing them to the end-user. The entities involved in our supply chains include suppliers, manufacturers, warehouses, freight companies and distribution centers.

Traceability is the key issue with pharmaceutical supply chains, the supply chain must maintain full control of every step of the process, starting with all the ingredients required to manufacture the product, by way of risk analysis mapping, and technical agreements with each external entity involved in the chain, and routine facility audits.

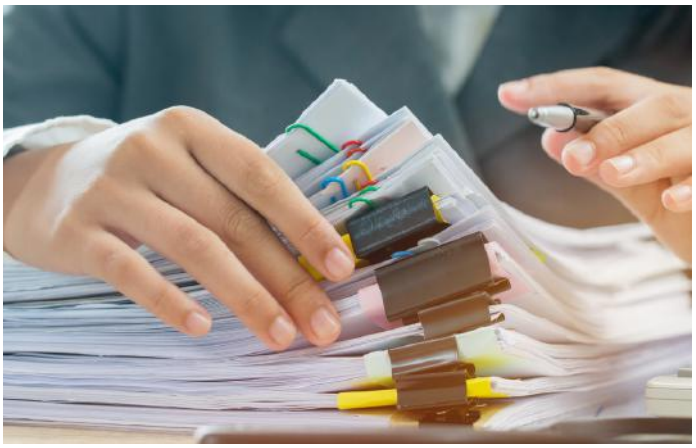
Key Tasks

1. Control of whole supply chain from starting material through to end customer
2. Risk Management analysis of the supply chain
3. Ensuring compliance with QMS throughout the supply chain
4. Ensuring traceability at all times

REGULATORY

Our Regulatory teams work hard to ensure your products are safe to distribute.

Regulatory affairs is a profession developed from the desire of governments to protect public health by controlling the safety and efficacy of products in areas including; pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines, and by the companies responsible for the discovery, testing, manufacture and marketing of these products wanting to ensure that they supply products that are safe and make a worthwhile contribution to public health and welfare.



Key Tasks

1. Collation of required documentation to prepare the dossier submissions
2. Due Diligence of dossiers if requested
3. Provide Gap Analysis report on performed Due Diligence if requested
4. Preparation collated documentation into eCTD
5. submission format
6. General advice on variations and regulatory procedures

COMPLIANCE

Our compliance teams work alongside the Quality Assurance teams within the QMS to ensure that all the pharmaceutical regulations are adhered to.

Pharmaceutical Compliance plays a critical role when it comes to pharmaceuticals and their use. The chief reason for its importance is to ensure the health and safety of those who use the products.


Pharmaceutical science is very exact and when there is any type of noncompliance, disaster can ensue. There have been many reported instances of patients who have died due to receiving a wrong medication or the wrong dosage of the right medicine. Most of the time, these incidences can be attributed to the lack of pharmaceutical compliance.
Compliance officers will spend their time researching new or updated regulation, updating their colleagues and ensuring the QA team implement any new documentation required.

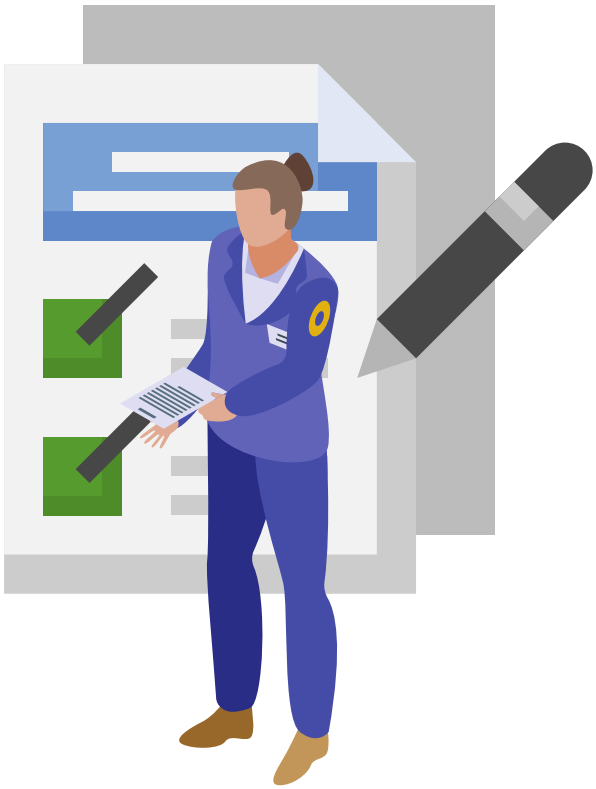
Key Tasks

1.Monitoring of regulation changes and law changes in relevant territories

2.Monitoring of review dates on current controlled documents

3.Monitoring of the audit schedules and highlight due audits

4.Working with Quality Assurance teams to update relevant documents as identified



COMPLIANCE CONTROLS

We navigate the compliance landscape of handling pharma products in Europe and the UK. The safety compliance surrounding the manufacture, import, sale and distribution of human medicines and active ingredients is covered by a number of legal instruments for which licences to operate are required.

We have documentation that covers this topic of compliance including the following;

- **Marketing Authorisation Holder (MAH)**
- **Wholesale Distribution License (WDA)**
- **Manufacturer Importation Authorisation (MIA)**
- **(current) Good Manufacturing Practice (c.GMP)**
- **Good Distribution Practice (GDP)**
- **Active Pharmaceutical Ingredient License (APIA)**
- **Specials Approval**
- **Named Patient Approval**
- **Qualified Person for Pharmacovigilance (QPPV)**
- **The Responsible Person (RP)**
- **The Responsible Person Import (RPi)**
- **The Qualified Person (QP)**
- **Auditing**
- **Quality Management System (QMS)**

We also can provide a number of fact sheets and explanation documentation on each of these topics for a more detailed analysis and deeper understanding of compliance requirements.

QUALITY MANAGEMENT

At IPG we have our own Quality Management System.

A quality management system (QMS) is defined as a formalised system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. Our QMS helps coordinate and direct an organization's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis.

In terms of Pharmaceutical QMS the following regulations are adhered to 2003/94/EC the GMP directive and 2001/83/EC as amended.

Key Tasks

1. Management and creation of the Controlled Documents, SOPs, Policies
2. Management of Change Requests
3. Management of Supplier/Customer approval processes
4. Management of Technical Agreements
5. Management of Audit Schedules
6. Management of Annual Product Quality Reviews (APQRs)

PROJECT MANAGEMENT

We manage our client relationships through one single point of contact.

Our client's one point of contact interfaces with our extensive teams that manage the planning, delegation, monitoring and control of all aspects of a project and the motivation of those involved to achieve the project objectives within the expected performance targets for time, cost, quality, scope, benefits and risk.

Project management is the application of processes, methods, skills, knowledge and experience to achieve specific project objectives according to the project acceptance criteria within agreed parameters. Project management has final deliverables that are constrained to a finite timescale and budget.

A key factor that distinguishes project management from just ‘management’ is that it has this final deliverable and a finite timespan, unlike management which is an ongoing process.

Key Tasks

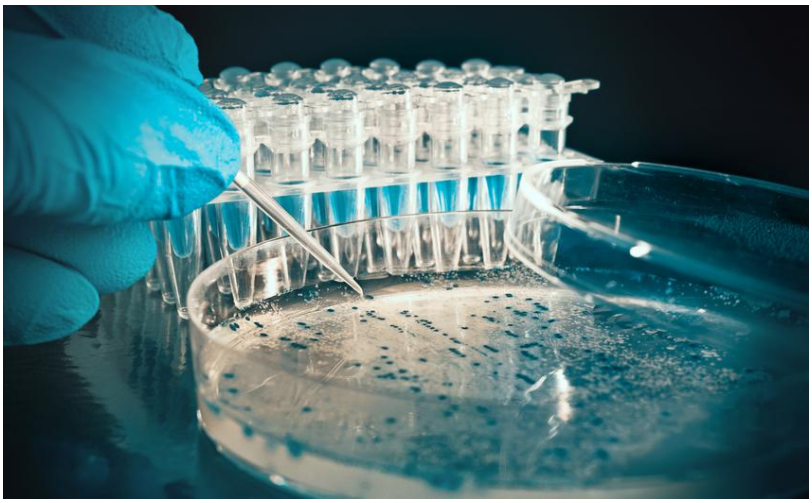
1. Activity and resource planning
2. Organising and motivating a project team
3. Controlling time management
4. Analysing and managing project risk

PHARMACOVIGILANCE

Pharmacovigilance (PV), defined by WHO as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem heavily focuses on adverse drug reactions (ADRs), which are defined as any response to a drug which is harmful and unintended, including lack of efficacy.

Pharmacovigilance is concerned with identifying the hazards associated with pharmaceutical products and with minimizing the risk of any harm that may come to patients.

Companies must conduct a comprehensive drug safety and pharmacovigilance audit to assess their compliance with worldwide laws, regulations, and guidance.



Medicines and Medical Devices have to comply to their respective Directives.

Key Tasks

1. Setting up of the Pharmacovigilance Site Master File (PSMF)
2. Literature searches on all active ingredients in a product
3. Individual Case Safety Reports
4. Handling Medical information requests
5. Urgent safety review and PRAC requests

BUSINESS DEVELOPMENT & LICENSING

At IPG, Business Development is the creation of long-term value for an organisation from its customers, markets and relationships.

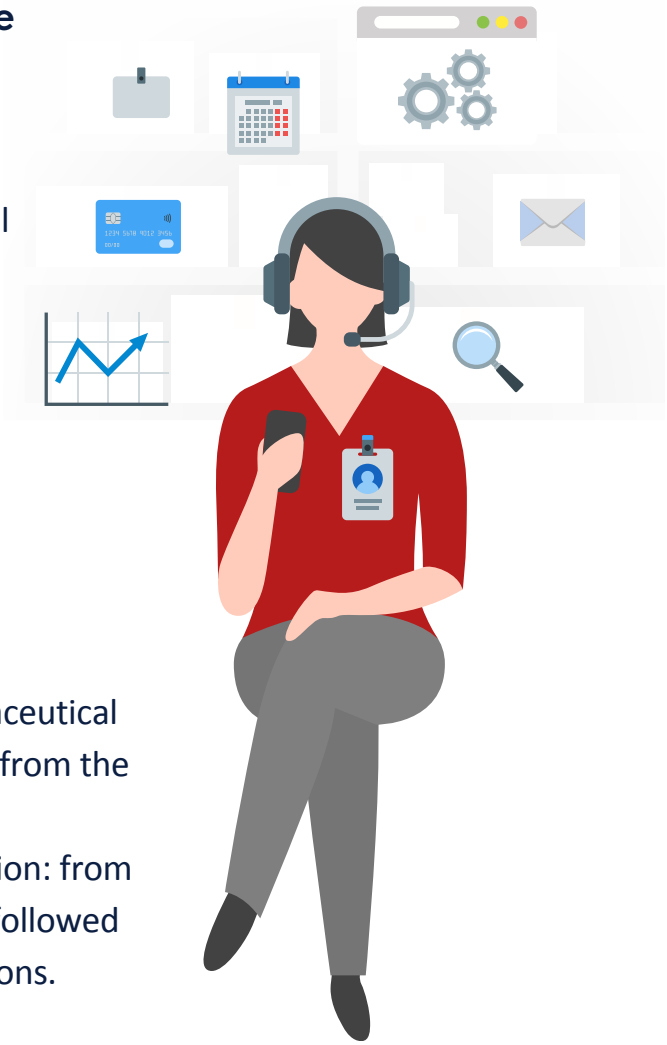
It's about creating opportunities for which value will persist over the long-term. By identifying new markets in which to reach new customers is one important gateway to creating this long-term value. Business development is also about building, managing, and leveraging relationships that are based on trust, respect, and a mutual appreciation.

We undertake assignments to locate, negotiate and close licensing deals across the globe. With regards to licensing, please refer to the licensing case study above.

We also offer Procurement services in the way of of sourcing and selecting vendors, establishing and negotiating payment terms and contracts while also actually purchasing of the goods from an external source. Procurement are concerned with acquiring all the goods and services that are important to an organisation.

TECHNICAL TRANSFER

Manufacturers often have multiple buildings on a single campus, in which case a technology transfer can simply be a move from building to building.



Technical Transfer is applied when a pharmaceutical company wants to change from an existing manufacturing site to a new manufacturing site. More generally, it can also involve the move from one process train to another, or perhaps from one facility to another. A technology transfer always implies a move from some other manufacturer to our manufacturing site.

Assuming that the raw materials and Active Pharmaceutical Ingredient (API) remain the same and are procured from the same supplier, a technology transfer begins with an assessment of the original manufacturer's information: from raw materials through critical process parameters, followed by performing equipment, backsides, and comparisons. IPG has a comprehensive operating procedure.

OUR CENTERS OF EXCELLENCE

United Kingdom
(Bracknell & Newcastle)
Technical Operations, Commercial,
Project Management

New Zealand
(Wellington)
Logistics, Strategy

China
(Shenzhen)
Sourcing, Auditing

Canada
(Toronto)
Global Marketing

ice pharma group

Corporate Slide Deck

2 Venture House, Arlington Square, Bracknell, Berkshire, RG12 1WA
Email: info@icepharmagroup.com, Web: www.icepharmagroup.com