



IP Focused Research & Investment Banking



SkyQuest Regulatory Services

Are Regulatory Requirements Puzzling You?



How do I penetrate multiple markets quickly and efficiently?

How do I ensure a successful audit



What are the local regulatory issues?

What is the cost of regulatory approvals

What is the shortest achievable time to market ?

What is the correct coding applicable to my product

Our experts do more than identify deficiencies or highlight areas where you're at risk. We engage in hand-holding with our clients to see them through product approvals.

SkyQuest Regulatory Solutions



Strategic Partner Identification in New Markets, Deal Negotiation & closing, Sales Monitoring through our Global Healthcare Innovations arm

6. Distributor Search and Qualifications

Define Regulatory Status, Determine Classification, Regulatory Route, Ensure compliance

1. Regulatory Consulting

Gap Analysis & preparation for Audits by Regulatory Agencies, Compliance to GMP & ISO Systems

2. Quality Systems

Design clinical study & protocols, Study Execution, Site Monitoring Trial Management through our Investigators Forum Network Arm

3. Clinical Studies

We assist companies of all sizes to put the pieces of the puzzle together to meet the requirements for their products

5. Reimbursement

Determine Existing Codes / getting new codes, Define reimbursement strategy, Access to various reimbursement channels

4. Regulatory Submissions

Preparation & Submission of Dossier, Authorized Representation, Follow up on submissions, liaison to regulatory authorities



Sectors Served

Pharmaceuticals & Biopharmaceuticals

- New Chemical Entities (NCE)
- Generics
- Biologicals
- Vaccines
- Biosimilars

Medical Devices & IVDs

- Invasive / Non-Invasive Devices or Diagnostics
- Implantable Devices
- Novel Drug Delivery Systems

Cosmeceuticals

- Dermato cosmetics

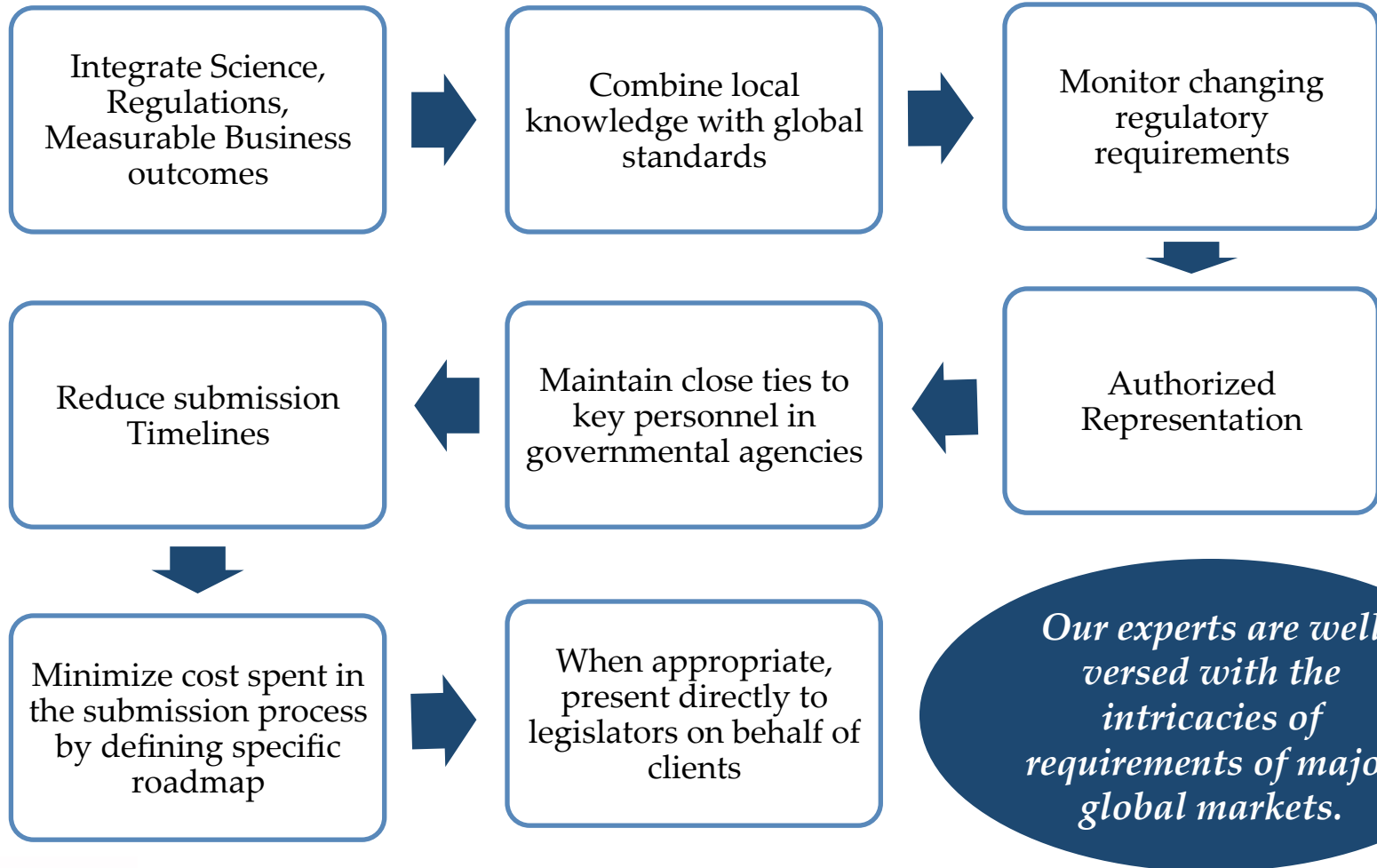
Nutraceuticals

- Food Supplements

Regulatory solutions across USA, EU, Russia, South Korea, Australia and Emerging Markets to obtain necessary product approvals



Our Approach



Markets Covered – North America



USA & Canada

Our team has in-depth knowledge on how to submit these applications and has developed strong relationships with the FDA & Health Canada officials over the years

US FDA & Health Canada Approvals

- Submission preparation for product 510(k), Pre Market Approval (PMA) etc.
- ANDA/NDA/DMF Submissions
- STED preparation, MDL Approval (Canada)

FDA Audits

- Know from our experts
- What to expect during the audit
- Interpret the findings
- Solutions to prevent regulatory actions

Reimbursements

- Our reimbursement experts provide you with in-depth coding & coverage information.
- Assistance in accessing reimbursement channels like Department of Veteran Affairs Formulary (DVA), Department of Defense (DoD), etc.



Health
Canada

Santé
Canada





Markets Covered – EU

SkyQuest provides a full range of EU Regulatory Affairs and Quality Assurance Services from launching new products to supporting maintenance activities
We also have the provision of European Authorised Representative Services to non-European manufacturers

Medical Devices

- Technical File compilation, CE Marking, Auditing
- Liaison with EU Competent Authorities, Notified Bodies and Regulatory Authorities, including assistance with site audits
- Ensuring compliance to required quality systems like ISO 9001:2008 and ISO 13485:2003

Human & Veterinary medicinal product

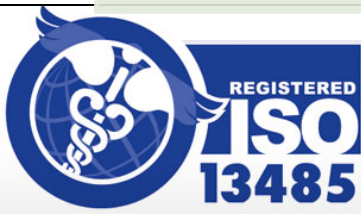
- National/MRP/DCP/ Centralised submissions
- Liaison with Competent Authorities

Cosmetic products

- From 11 July 2013, all manufacturers and distributors of Cosmetic products must be compliant with the European Cosmetics Regulation 1223/2009.

EC

REP



Markets Covered – ASIA



Asia Pacific region is a rapidly growing and lucrative market in the health care sector.

Support your medical device regulatory compliance efforts in China, India, Australia, Taiwan, Singapore and South Korea

“On the Ground” presence being critical for these markets our local offices can act as your local representatives.

We also support submissions in other South East Asian markets including Thailand, Vietnam, Philippines and Indonesia.

SkyQuest experts are well versed with the rapidly evolving regulatory environment in these markets



China Food and Drug Administration



Markets Covered – MENA



Israel

From our office in Herzelia, we can assist you with product registration and serve as your Israeli Registration Holder to liaise with AMAR, Israel's Ministry of Health

Saudi Arabia & UAE

The Kingdom of Saudi Arabia (KSA) Food and Drug authority (SFDA) 's regulatory infrastructure for medical device registration is still under construction. SkyQuest experts help you with SFDA & UAE MoH submissions and approval

Egypt

SkyQuest experts are experienced in dealing with the bureaucratic procedures and communication issues while dealing with Ministry of Health and Population (MOHP). We assist you through the complicated registration process to ensure smooth approval.

Markets Covered – LATAM



SkyQuest Technology Group has extensive experience handling product registrations in key Latin American markets like

Mexico : *COFEPRIS*

Brazil: *ANVISA*

Argentina: *ANMAT*

Our experts have the know-how and resources to fully assist you in preparing and submitting applications to **COFEPRIS, ANVISA and ANMAT** as well as distributing and marketing your product in the country.

SkyQuest also assists clients in handling Brazilian GMP Audits



Additional Services Offered



Commercial Feasibility

Pre-Launch Assessment

Usability Studies

Government Multilateral Procurement

Why SkyQuest



Combined expertise of the network domestic and international alliances allows access to multiple markets from single point

- Active involvement by an experienced team, dedicated to helping your company to successfully develop and execute its plans

Comprehensive support, tailored to the specific needs of the organization of any type (from start-up to well-established, small-sized to MNCs)

- One Stop solution to entering new markets

Experience with successful product registrations of innovative products that follow no clear pathways

- Expertise in wide range of therapeutic categories, Improve client's regulatory track record and speed to market

Our Network Worldwide



■ *Global offices* ■ *Global partners* ■ *Affiliates*

The background is a solid green color with a subtle grid pattern. There are several abstract, curved shapes in a lighter shade of green, creating a sense of depth and movement. In the top left corner, there are a few small white dots and a faint circular shape, possibly representing a lens or a light source.

Expert Team

Our Regulatory Experts



Dr. Subodh Adeshra

One of the longest serving FDA State Commissioner in India with immense experience in Pharmaceutical Manufacturing, Medical Devices product approvals & quality requirements

Mr. David Oh

Brings in over 15 years of experience from diverse areas of Sales & Marketing, Institutional sales, Branding, Technical Support, Regulatory approvals & clearances to get products into the Korean Market

Mr. David Furst

Over 17 years of experience in Lifesciences domain. He also brings in considerable experience reimbursement in Europe and the USA through his role as director at Mediclever, a professional reimbursement consulting services

Our Regulatory Experts



Mr. Kenneth Lafferty


Expert in USFDA regulations and reimbursements . He has authored and been an invited speaker at many manufacturing, professional medical society meetings on the topics of Reimbursement and Healthcare Care Policy

Ms. Patricia Trifunov

Brings over 20 years of expertise from State and Federal Politics, Business & Strategies, Health Systems Management, Government & Public Relations, Sales Management, Contract Negotiations & Pricing. Has worked with leading companies like Abbott Labs, Schering Plough, & Glaxo Smith Kline

Ms. Mary Ryan

Brings in more than 10 years regulatory affairs experience from decision making role within manufacturing and as Operations Manager / Director for UK Notified Body, and 18 years in quality assurance . Has handled clients from 40 countries in a capacity as Management Representative / Client Liaison of 'Regulatory Advisor

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About Our Organization



About Us

SkyQuest Technology Group is a Global Technology Aggregator & Accelerator is profoundly engaged in innovation ecosystem with myriad stakeholders in various capacities helping them leverage external sources of R&D and create value from intellectual property. It operates by way of:

SkyQuest Technology Consulting Pvt. Ltd., INDIA

Research, Investments, Technology Transfer & Market Entry (India, Israel, MENA)

Skyquest Technology Ventures, USA, CANADA

Investments, Technology Transfer & Market Entry (NA, EU)

SkyQuest IRN Associates Inc., CHINA

Research, Investment, Technology Transfer & Market Entry (China, Far East & ASEAN)

Investigators Forum Network, INDIA

Low-cost Clinical Development & Usability Studies for New Tech

Global Healthcare Innovations, INDIA, CHINA, EU, NA

MedTech Regulatory Affairs & Distribution management (India, China, ASEAN, EU, NA)

Ingenuity Ventures, EMERGING MARKETS

Early Stage Investments in Health & Nutrition, New Energy, Water tech & Agriculture



Affiliates

- **Asia Pacific Business and Industrial Systems Inc., PHILIPPINES**
- **BioNegev Clusters, ISRAEL**
- **Carbon First Consulting Ltd., UK**
- **Israel Export International and Cooperation Institute (IEICI), ISRAEL**
- **Laser Consult, HUNGARY**
- **Shanghai Technology & Transfer Exchange, CHINA**
- **South-South Global Assets & Technology Exchange (SS GATE)**
- **State Agency for Technology Innovation, VIETNAM**
- **Sinew Consulting, TAIWAN**
- **ECEB Networks, DigiMEF Ltd., UK, SWITZERLAND & CHINA**
- **Patentica, RUSSIA**
- **Industrial Technology Research Institute (ITRI), TAIWAN**
- **WWF – India, INDIA**



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merci beaucoup

obrigado

dank u wel

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danke schön

धन्यवाद

спасибо

Thank You

謝謝你

ありがとう

grazie

teşekkür ederim

شکرا

děkuji

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