Pure Global

CRO SERVICES
BEYOND BORDERS

PureVision AI, Inc. DBA Pure Global
www.pureglobal.com

The Challenges of Medical Device Registration

Complex Product Access Process

Difficult Interfacing with Multiple CROs

Difficult to Obtain Market Research Data

Incomprehensible Local Regulations

Complex Government Bidding Information

Limited Access to Competitors' Clinical Data

Difficult to Obtain IFU for the Similar Product

Certificate Mismanagement Leads to Expiration

Discovering Reliable Distributors

Locating Reliable Labs

Finding the Registration Data of Similar Products

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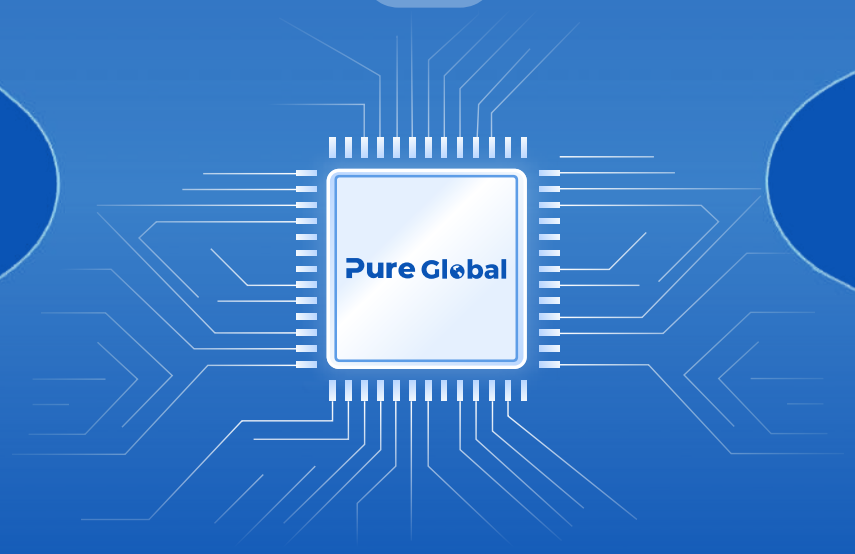
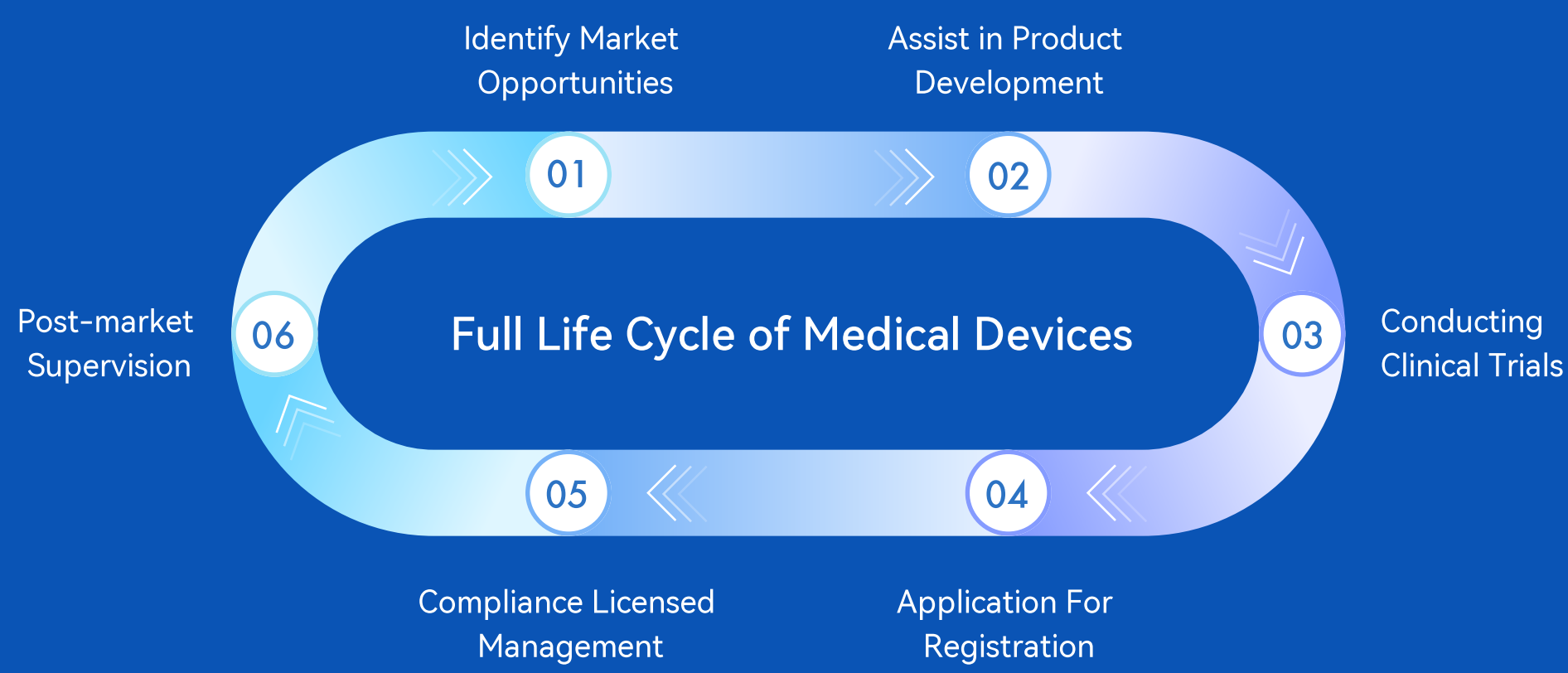


Full Process of Solutions From Pure Global

We have a top-notch expert service team, with extensive regulatory certification and clinical experience, that uses AI technology to provide one-stop medical device export services through our global service network



Identify Market Opportunities & Assist in Product Development

Have you encountered these troubles when developing your product strategy?

Ambiguity in R&D Direction

Inaccurate judgment of market trends, resulting in unclear direction of product development and stagnant progress

Elusive Competitive Landscape

Difficulty in obtaining information on potential competitors' main products, financial and marketing strategies

Challenges in Market Potential Forecasting

Need to understand the macroeconomic situation and various indicators data of the local medical market

Pure Global Solutions

1 On 1 Expert Consultation

Big Data-Based Market Research Report Services

Global Medical Device Regulatory, Clinical, Institutional Database

- Market Access Consulting
- Market Competition Strategy
- Analysis of Potential Market Growth
- Market Size Analysis
- Main Products and Manufacturers
- Consumer Demand Analysis
- Global Medical Device Database
- Purchase and Sale's Channels

Conducting Clinical Trials

Hard to find reliable overseas clinical services

Difficult to Find Quality Clinical Teams

Often encounter uneven quality of clinical teams and confusing project management

Lack of Global Clinical Resources

Lack of quality global clinical resources, difficult to guarantee the quality of labs and biological samples

Unclear Clinical Trials Progress

Project progress follow-up is not timely, project reporting is slow and not transparent

Pure Global Solutions

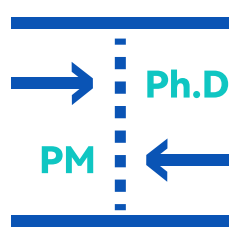
Expert Team

Our team consists of highly qualified experts with years of experience in clinical trials, biostatistics, clinical study, regulatory compliance, clinical data and vigilance

Global Clinical Resources

Our extensive network of clinical trial sites and biobank projects in Europe and America enables us to offer a variety of clinical services

Dual Ph.D. / PM Mode



Our projects implement a dual Ph.D. and dual PM senior staffing model, to ensure clinical professionalism and project management.

Clinical Criteria Followed

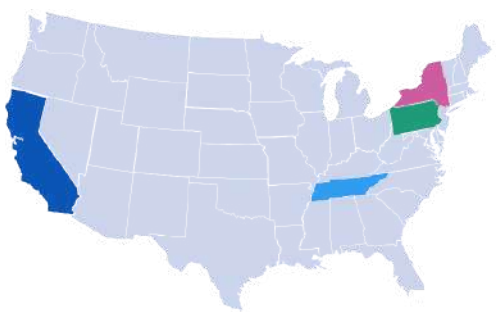
ISO 17025

EN 13612

ISO 20916

ISO 14155

Clinical Research Sites



United States

New York

- CLIA & CAP Certified
- Immunodiagnostic Tesgts
- Multiplexing Technologies
- Decentralized Clinical Studies
- Rapid-response Patient Testing
- Analytical & Clinical Validations

Pennsylvania

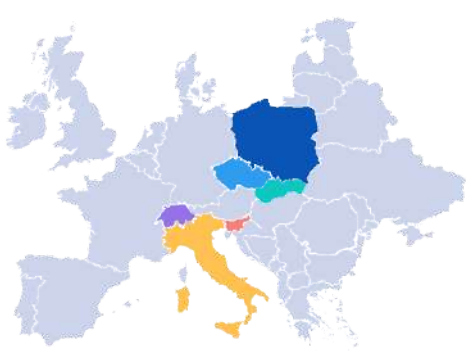
- CLIA & CAP Certified
- Next Generation Sequencing(NGS)
- Digital Pathology
- Circulating Tumor Cells
- Analytical & Clinical Validations

Tennessee

- CLIA & CAP Certified
- Fully Licensed and Accredited by Many States
- GI Pathology Laboratory
- Cytogenetics Training Program
- Analytical & Clinical Validations

California

- CLIA & CAP Certified
- Clinical Genetics Laboratory
- Analytical & Clinical Validations
- Usability Studies



Europe

Switzerland

- ISO 17025
- Clinical Chemistry
- Microbiology
- Infectious Serology

Italy

- University Laboratory
- Diagnostics test research
- Analytical & Clinical Validation Studies

Poland

- ISO 17025
- Analytical & Clinical Validations
- Usability Studies

Slovenia

- AACI & ISO 9001
- Hospital Patient Recruitment Access
- Analytical & Clinical Validations

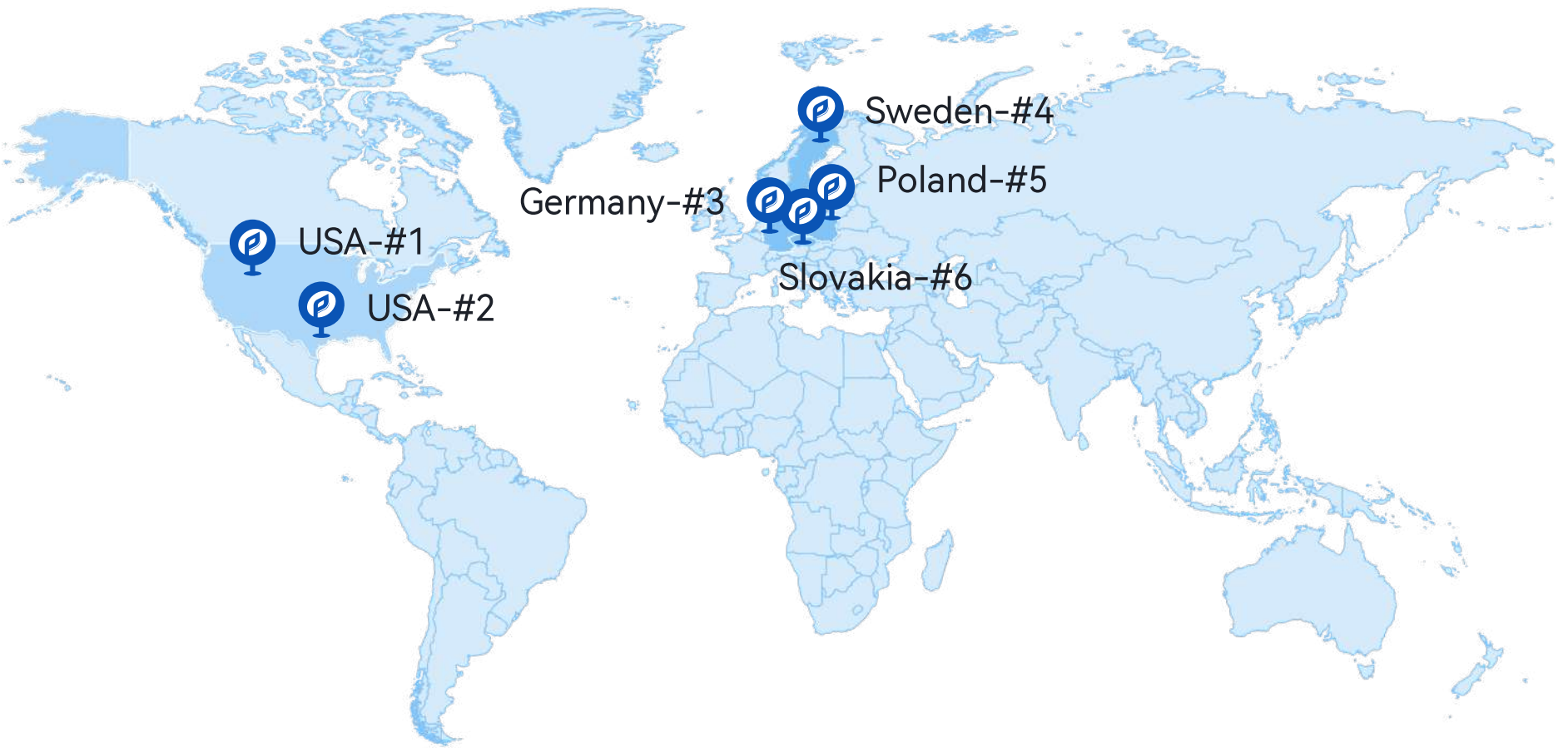
Slovakia

- Network Clinic Patient Recruitment Access
- Clinical Validations

Czech

- Network Clinic Patient Recruitment Access
- Clinical Validations

Biobank



Our company has a total of **6 biobanking projects** worldwide that are currently collecting various types of samples on an ongoing basis. Additional resources are being approached to help us both expand our operations both horizontally and vertically in terms of numbers of samples and sample types.

US	EU	BIO-BANK
✓	✓	Upper respiratory tract microbial swab samples
✓	✓	Blood samples for infectious diseases
✓		Stool samples
✓		Urine samples
✓		Tumor tissue samples

More sample types in development...

Global Market Access

Have you encountered these problems during the medical device registration phase?

Unclear Alignment Path

With unclear alignment paths, it is essential we explore the overseas access path every step of the way and learn as we go.

Difficulty Understanding Regulations

The laws and regulations are complicated and complex, and the language and culture are very different, so it is not easy to read and understand them completely.

Lack of Local Representation

Having proper local representation overseas is a critical step for successful market access.

Pure Global Solutions

Global access experts will tailor their services to your business and products, responding to customer questions and providing comprehensive solutions at any time during the product registration process

Experienced global access experts to plan the best path for your overseas registration

Global Regulatory Intelligence Platform(GRIP), combine AI and big data technology to generate product manuals and other documents with one click to reduce costs and improve efficiency

We act as an independent in- country representative with offices globally, to help ourclients maintain control of their device registrations

Multi-country captive companies, with a single authorization, your problems can be solved in a timely response

Service Scope

We are now able to provide full medical device registration certification support in multiple countries/regions including: EU, UK, Switzerland, Canada, USA, Mexico, Peru, Brazil, Colombia, Egypt, Australia, Malaysia, Singapore, Japan, Saudi Arabia, Thailand, Indonesia, Vietnam, as well as the Hong Kong, Macao regions of China, etc.

Service Process

Regulatory Strategy & Market Access Consulting

Technical Documents Compilation, Submission and Management

Post-Market Surveillance & Vigilance Solution

Multi-Market In-Country Representation

IFU.ai

Demo Request

First in the Industry, AI automatically generates product instructions for use（IFU)

Pure Global introduce AIGC technology，is the first new product in the "automatic generation service of regulatory document" .

- AI training data from millions of documents
- Covering all types of medical devices
- One-click automatic generation
- Bilingual support in English and Chinese

Compliance Holding and Post-listing Supervision

What about the low efficiency of product certificate management?

Expiration Date Monitoring

Many compliance management matters, inefficient communication; untimely human monitoring, resulting in expired certificates/ registrations

Difficulty in Managing Certificate Clutter

Problems such as loss, duplication and errors caused by cluttered certificate information and personnel flow; multiple files cannot be managed centrally

Slow Response to Overseas Market

Slow response time to issues such as changes in local regulations that require certificate updates and product complaints

Pure Global Solutions

Track CRO service progress and licensed management systematization

01

Pre-licensed

- Expert team reports regularly and responds to project progress in a timely manner
- iScheduler convenient for customers to view online (applet + web) and track project progress

02

In Licensed

- GRIP supports multi-document granular management and one-stop expiry reminder
- Professional team can manage on your behalf

03

Post-listing

- Local representatives handle regulatory issues in a timely manner，Dual PM Delivery Process
- GRIP supports 60w+ global compliant distributors

Success Stories

- 50+ Years of overseas clinical certification experience
- We are the CRO with the most List A clients in the world
- 100+ European and American Registration Certificates
- We have engaged with half of the EU HSC category A list
- Several successful overseas clinical NMPAs
- Dozens of European whitelist US EUA emergency success stories
- Hundreds of global registration certificates

Scan For Success Stories

Global Growth Partner to MedTech Companies

We have passed the BSI ISO 13485 quality system certification from the BSIA team of experts with Regulatory Affairs Certification

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