The Registration Data System, and the Selection of Target Market Entrance

Registration Data Consists:

- Basic Registration Data: 5B, Toxicology, Phy-chem properties
- Standardized format data: COA, Misc. Templates
- Fundamental Info: CIPAC, Pesticide Manual, AmisGlobal, etc.
- Registration Requirement: Requirement, file checklist, registration records
- Standard legal documents: LOA, reg. Agreement, confidential agreement, permit
- Standard procedure and master plan: Design accordign to company practice

** To different types of companies, the focus and directions should be different*

Registration Data will contribute to:

- Feasibility judgement: Can we achieve the requirement? What's the budget and timeline?
- Registration support: Support the registration projects of the company, especially the independent registrations.
- Market Analysis: Determine the entry barrier of the market, analyze the customer quality by registration records
- Risk control: Cost-turnover analysis, Risk control in authorization safety and core data leakage.

2. Basic Data_Legal Compliance and Data availability

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Technical product:

1. **Plant certification**
   - 1.1 China local manufacturing license
   - 1.2 Relocation possibilities
   - 1.3 ISO system
   - 1.4 Hazardous chemical certification from China authority
2. **China local registration**
3. **Content compliance with Global registered products**
4. **No patent issue**
5. **Stable production**

Technical product:

1. Chemistry of product
   - 1.1 Manufacturing process
   - 1.2 Inpurity justification
   - 1.3 Product quality examination report
   - 1.4 Full analysis of ingredient of TC (CIPAC method, titration method analysis for the A.I.)
2. Introduction of product
3. Physical chemical properties report
4. Toxicology report
   - 5.1 Acute oral toxicity, acute dermal toxicity, eye irritation, dermal irritation, sensitization
   - 5.2 Ames test, micronuclues test
5. Environmental studies

Formulated product:

1. Chemistry of product
   - 1.1 100% composition
   - 1.2 Product quality examination report
   - 1.3 Heat Storage stability (for both formulation)
   - 1.4 Packaging of product
2. Toxicology report
3. Efficiency
   - 3.1 Mechanism of action
   - 3.2 Demonstration trial report
4. Environmental eco-toxicology
5. Label

3. Standardized format Data

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➢Factor 1: Which data belongs to “Standardized Data”?

- ✓ COA; Specification; Composition and Recipe; Analytical method
- ✓ What means “In GLP format” and how to achieve?

➢Factor 2: Key Observations of “Standardized Data”

- ✓ Comply with format of destination countries: E.g.: Product COA by Malaysia, CNAS COA by Colombia
- ✓ Comply wih international guidelines: FAO requirement, identification of tox impurities, Formulation spec control and solvent control
- ✓ Comply wih commodity products: The harmonization between global/domestic standard
- ✓ Compliance in submissions: Same data dossier to all cutomers/submissions

➢Factor 3: Sources of “Standardized Data”

- ✓ Understand FAO requirement, and checklist in practice;
- ✓ Consistency with reference data: 5B impurities, phy-chem properties, toxicity category

➢Factor 4: Utlisation of Templates

- ✓ GLP guideline, and its realization in the data dossier
- ✓ Understanding the “suitability” of template (Kenya, Paraguay, Guatemala case)

4. Source and Application of Fundamental Information

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- **Registration Guideline and Requirements**
  - Legal documents requirement may be acquired from official websites
  - Data checklist normally provided by customers, but need 3rd party verification
- **Record of Registered products**
  - EU, USA, Australia: Check through official websites/records
  - Japan, Koream Latin America: Available in local languages. But can check through "key word" by Google.
- **Basic Information to fill the Application Form**
  - FAO specification: Phy-chem data, QC items, Impurity limits
  - EPA RED report: Toxicological data, Eco-tox data, Environmental behaviour
  - Pesticide Manual: Phy-chem data, toxicological data, eco-toxic data
  - EXTOXNET/Inchem: Tox data, metabolism information
- **Analytical method/Residue Analysis Method**
  - CIPAC, AOAC manuel
- **Efficacy Data, Label, MSDS**
  - google MNCs label, and public MSDS
- **Synthesis Pathway**
  - Patent files, and domestic journals and publications

5. Legal Documents

➢Major Legal Documents in Oversea Registrations:

1.LoA: Identify the position of the authorizing company; May retreat, Logical and precise in expression

2.License and Permit: Identify the legal Production, Registration, Sales. Consistency in Info

3.Format Agreements: Beneficial to ourselves, and restrict the rights of the oversea customers

E.g.: Non-exclusive, and right for "Third Party Authorization"

How can customer acquire the data? Use or Access?

➢Key Points of Legal Document System:

1.Compliance of documents: All legal documents should consist a complete logical chain, to identify the legal Production, Sales, Registraiton, Authorization and Supply (5 Aspects)

2.Compliance in legalization: Comply with local authority requirement, but "with exception"

3.Logic in Submission: GLP compliance, sample tracing, consistency in content expression, consistency in report essentials, and consistency in sponsor/manufacturer information

4.Compliance in Permits: Address, Content, Time, and compliance with oversea equivalance file (see Malaysia and Argentine case)

6. Registration Plan: The Selection of Product and Target Market

Principle of Expansibility

Principle of Suitability

Principle of Registerability

Principle of Suppliability

1. Opportunity/Potential of New Product/Business

1.1 Analysis of Current Situation

1.1.1 Market Size

1.1.2 Competition Anal

1.1.2.1 Major Competitors

1.1.2.2 Market Share

1.1.3 Margin Analysis *(Pricing, Average margin ratio)*

1.2 Future Development

1.2.1 Market size

1.2.2 Competition

1.2.3 Margin

2. Synergy Analysis

3. Registerability Analysis

3.1 Data Required

3.2 Time & Cost

4. Suppliability Analysis

5. Estimation of Resources Required

6. Conclusion and Suggestion

7. Project Plan

7.1 Business Model

7.2 Action Plan *(Timelines & Activities)*

7. Key Factors of Country Selection:

➢ Determine the Key Countries

1.Joint consideration of Market size and the control power of the company

2.Consideration of current regstratin data and acceptable data/registration cost

➢ Registration mode

1.Establish entities to hold registrations: Entry Barriers, Limitation for capital injection/retreat, Requirement for local staff.

2. Authorize customer: How to control registrations, and further restrictions

3. Contract consulting firm: The responsibilities allocation between consulting form and manufacturers (Data vs Procedure), Holding of registration certificate and transferring posibilities. (like Malaysia, can not transfer)

➢ Determination of Bottleneck, Time and Cost

1. Technical “Turn Key” Registration: India

2. Equivalance Registations: Australia, Brazil, USA, Mexico, EU原

3. Source Registrations: USA, Japan, Korea

7. Key Factors of Country Selection:

Regulation Factors

- *Overview*
- *General Data Req.*
- *Bottleneck Q.*
- *Est. Cost*
- *Est. Timeline*

*Latin America Case

- **Caribbean Countries:**
  - ✓ More strict trends, and to equivalance registrations
  - ✓ More difficult undet updated regulations
  - ✓ More monopoly from MNCs
  - ✓ Government relationship becomes a major factor to promote the local registrations
- **ANDINA countries:**
  - ✓ Relatively easy, no need for GLP lab data
  - ✓ Requirement to QC result, need CNAS lab test report
  - ✓ "Source registration", open a window to China companies
- **MERCUSOR**
  - ✓ Mature reg system based on equivalance
  - ✓ Huge differences in member countries (CHL, ARG, URU)
- **Brazil**
  - ✓ Complex requirement and long waiting list
  - ✓ Demanding on data format and equivalance
  - ✓ Less competition for registered products, high margain

8. Key Factors of Product Selection:

Internal Factors of Product Selection

- **Sales Regions:** Know the current revenue layout, and consider the trend of regulation and product development trend
- **Product Competency:** Consider the data availability, and company strength in this product
- **Development Trends:** Regulation trend: Ban/Restriction, Residue, Risk Mgmt
- **Future Drive:** Can form the synergy with current portfolio ? Or can the new product contribute to current business?

External Factors of Product Selection

- **Domestic Capacity and Competition:** Plan the competitive plan, and promotional approach of the product (pricing, formulation launch etc.)
- **Oversea Demand Analysis:** Analyze the demand of key market, and the substitution/synergy products situation.
- **Bottleneck of Registrations:** GLP data situation, Feasibility in equivalance, Patent situation

9. Determination of Registration Plan

➢ Determination of the Registration Cost

1. Calculate the registation cost for different countries (Admin fee, Local Tests, Maintainance, etc.)
2. Calculate the timeline for cost payment and reimburse
3. Estimate the acceptable Registration cost based on sales expection and profit.

➢ Risks

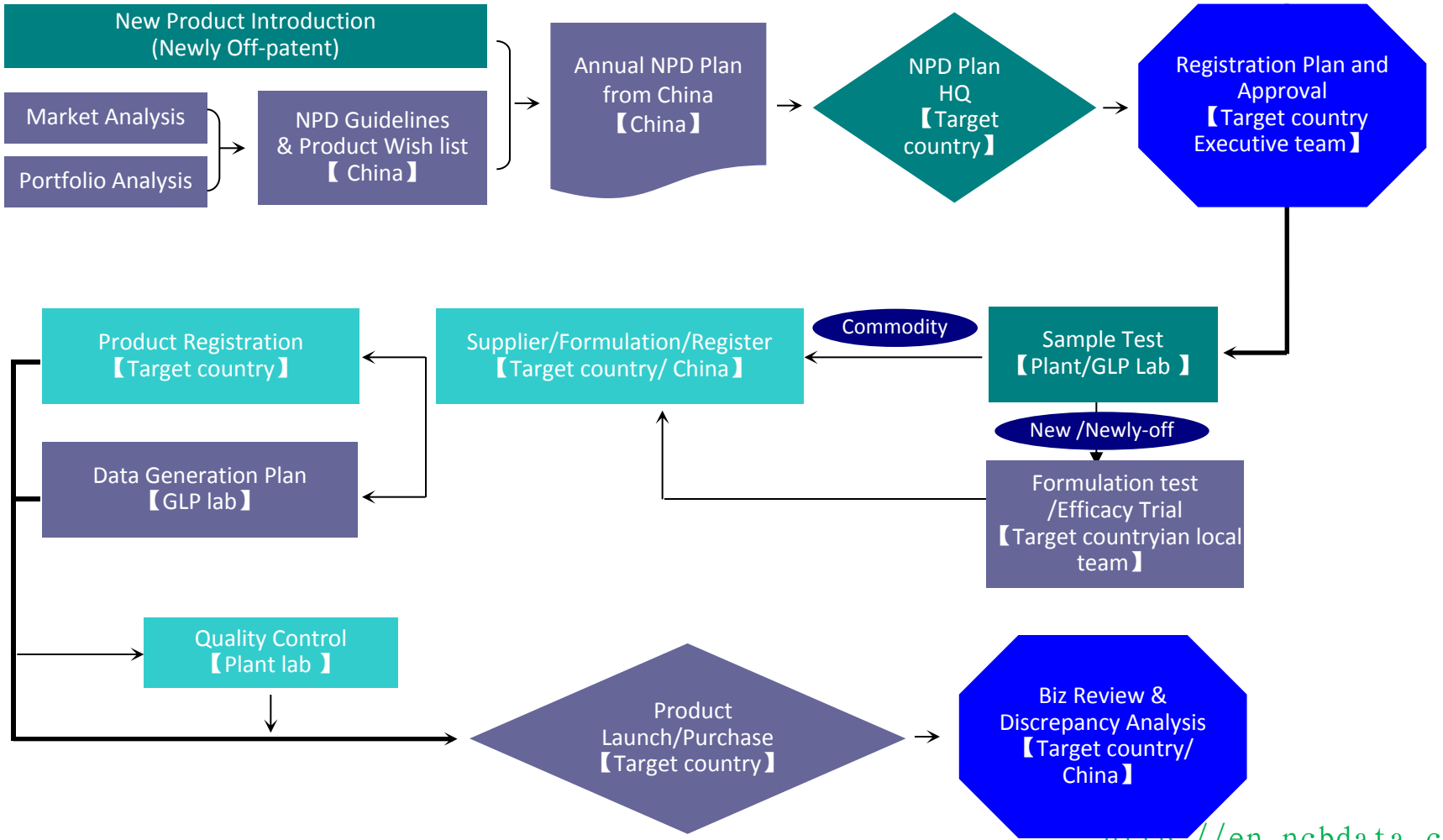
1. Patent Risk: Synthesis patent, Recipe/formulation patent, EU SPC， Borla exception clause,
2. Equivalance Risk: Content, Impurity profiles, Consistency in Registration and Export
3. Relocation risk: Need to maintain the consistency of site location during the registration process (Brazil requirement, and Rotem's case)
4. Authorization Risk: Data comfidentiality, control of customer, re-authorization/transfer

➢ Marker Suggestion from Registrations

1. Possibility of Mixture formulations
2. Registration Trends (may observed from the registration record)
3. Product Launch: From easy to difficult
4. Data Generation: From Difficult to easy (first of all: 5B report)

Example: Process of Strategic New Product Development

Strategic NPD plan serves long-term key products with promising market prospect, important to portfolio development of Target country market, and required more resource for registration. The Strategic New product registration plan need to be accomplished in 5 years.



Q &A ?

Thank you!