

Global Regulatory Strategy: The Asian Pacific Region

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Basic Issues

- The Biotechnology industry like others, has gone through a difficult economic time
- There are many opportunities available in the Asian Pacific Region
- The region has vast diversity
 - Geographical
 - Educational
 - Cultural
 - Economic
 - Regulatory/Procedural

Basic Issues (2)

- This diversity provides:
 - A source of leadership and support
 - A local presence
 - Global reach
 - However, challenges in product development
- Development of lifesaving/enhancing biotechnology products in the region
 - Provides local betterment
 - Supports global approvals and impact

Intellectual Property



- The Asian Pacific region:
 - Is a source of exciting intellectual property
 - Has expanding university and corporate infrastructure
 - Possesses availability of preclinical testing facilities
 - Has a growing number of clinical trial sites
 - Can offer competitive prices
 - Generates data of increasing quality
 - Allows for new horizons in disease treatment

Intellectual Property (2)



- A new pipeline of medical products will come from this region
 - Capabilities will have to be managed to meet ever-tightening regulatory requirements
 - There is increasing cooperation between individual Asian Pacific countries and FDA
 - Sophisticated oversight, review and documentation are necessary in the region

The Regulatory Climate



- In the West regulators are not very forgiving of poor quality data for medical products
- High quality data from any region will support product development and approvals/registrations
 - Chemistry, manufacturing and controls
 - Preclinical/nonclinical
 - Clinical
 - Facilities and documentation for developmental and testing

The Regulatory Climate (2)

- Application of appropriate resources for regulatory support for products is critical:
 - Internal expertise, properly directed
 - Trusted external support
 - Initiation of a development program that fits:
 - Product strengths
 - Efficient use of intellectual capital
 - Natural resources
 - The local economy
 - Training and experiences of workers
 - Quality and availability of facilities

The Regulatory Climate (3)



- Each concept must be examined closely:
 - Theoretical soundness
 - Practicality for needs of various regions
 - Regulatory hurdles
 - Perceived patient conditions
 - Indications desired by the innovator
 - Stability of final formulation (drugs)

Manufacturing

- The Asian Pacific region has a growing capacity
 - Small molecule drugs
 - Biologicals, including vaccines
 - Medical devices
- Labor is relatively inexpensive
- Both testing and commercial production possible
 - Developmental
 - Final products

Clinical Trials in the Asian Pacific Region

- Large population base
- Diverse ethnic origins
- Clusters of diseases (e.g., cancers, malaria)
- Temperate, subtropical and tropical climates
- Ethical requirements of local authorities differ
- Quality of clinical sites is widely disparate
- Careful handling of regulatory authorities and ethics committees is critical

Suggestions for Working in the Asian Pacific Region

- Initiate a developmental profile at the beginning
 - Initiate at the early discovery/prototype stage
 - Make objective “go / no go” decisions
 - Formally report data and results at each stage of development
- The results of the above may vary by sub-region
- Make sure that a training program is in place for:
 - Realization of consistent goals
 - Harmonization across the region and globally
 - Minimizing the expenditure of resources, time, money

Suggestions for Working in the Asian Pacific Region (2)

- Obtain assistance from experts:
 - They should possess technical expertise
 - They should have the capability of working in harmony with local experts
 - Caucus with them frequently for an integrated, independent and objective assessment across disciplines
 - Make sure chosen national sites and subregions can provide the resources and data quality required

Suggestions for Working in the Asian Pacific Region (3)

- Consider private/public/university partnerships:
 - They should possess technical expertise
 - They should have the capability of working in harmony with local experts
- Establish incubators
 - Supported by local governments and industry
 - Able to share utilities, educational, equipment and other resources
- Use appropriate outsource providers

Conclusions

- The Asian Pacific region has great potential for development of biotechnology medical products
- Careful planning in the regulatory and technical arenas with sensitivity to both national and subregions' needs is important
- Use an integrated product development approach with input from experts both from within and outside of the region
- Consider a careful analysis to generation of CMC, Preclinical/nonclinical and clinical data, taking into account quality, availability and cost

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