Benchmarking best practices and performance as a potential tool for increasing mutual trust

Dr. Navjot Singh, Partner, McKinsey & Company, New York Office
ICDRA – Singapore
29 November 2010
Introduction to McKinsey

- For over 75 years, McKinsey & Company’s primary mission has been to help clients achieve substantial, lasting improvements in their performance. We aspire to help leading institutions, private and public, improve their strategies, organizations and operations.

- McKinsey’s Healthcare Group serves clients around the world in the public, private and philanthropy arena. Through our work we have built global expertise in multiple healthcare systems and local market situations. We have also worked with healthcare regulators across the world.

- We also often pursue research in critical areas where this research can have lasting impact on overall performance of our clients.
Overview of presentation

Increasing complexity and globalization calls for increased collaboration among regulators

- Prioritizing potential areas of collaboration
- Introducing Project RegEx
The last decade has brought about tremendous change...

**Boom, bust and ? – DAX 30 example**

- Chart showing volatility from 2000 to 2010.

**Rise of many economies – China example**


**Increased connectivity**

- India cell phone penetration (per 100 people): 0.16 in 1999, 45.04 in 2009.

**Record budget deficits and national debt**

- UK budget deficit:
  - 1999: $13.8 billion surplus
  - 2009: $244.4 billion deficit
…including fundamental changes to the healthcare landscape

New diseases and epidemics

- SARS
- Avian flu
- Swine flu

Increasing burden of chronic diseases

US obesity rate

<table>
<thead>
<tr>
<th>Year</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999</td>
<td>15</td>
</tr>
<tr>
<td>2002</td>
<td>20</td>
</tr>
<tr>
<td>2005</td>
<td>25</td>
</tr>
<tr>
<td>2008</td>
<td>30</td>
</tr>
<tr>
<td>2009</td>
<td>30</td>
</tr>
</tbody>
</table>

Breakthroughs in research (somewhat…)

High tech meets healthcare
...and to the pharma environment

### Consolidation

- **Pfizer**
- **MERCK**
- **Sanofi**
- **Roche**
- **Abbott**
- **Takeda**
- **Pharmacia**
- **Wyeth**
- **Schering-Plough**
- **Aventis**
- **Genentech**
- **Alpharma**
- **Millennium**

### Commercial arms race – the end

**BIG PHARMA TO CUT MORE SALES REPS**

### Declining R&D productivity

#### Probability of success

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Probability of success</td>
<td>14.8</td>
<td>10.3</td>
</tr>
</tbody>
</table>

-30% decline

### Enhanced focus on drug safety

![Drug bottle and pills]
Industry is responding with many initiatives – R&D Example

- Improve R&D productivity
  - Fully leverage IT spend
  - Increase variabilization of costs and manage spend
  - R&D leadership development

- Close scrutiny of cost and speed
  - Closer scrutiny of cost and speed
  - Rethinking Performance Metrics

- Improve Decision-Making
  - Meta-Analysis of real world data

- Globalization
  - CER and Risk Benefit tools

- Enhance focus on compliance and quality
  - Enhance focus on compliance and quality

- Cross-disciplinary asset deep dives
  - Cross-disciplinary asset deep dives

- Increase risk sharing and minority stakes
  - Increase risk sharing and minority stakes

- Prediction Markets
  - Prediction Markets

- Optimize R&D total spend
  - Optimize R&D total spend
Clinical trials are increasingly outsourced to CROs and global

**Contract research industry revenue ($ billions)**

- 2000: 6.0
- 2010: 24.0

+15% p.a.

**Globalization of clinical trials – US example**

Percent of subjects enrolled in clinical trials – FY08 marketing applications for drugs and biologics received by FDA

- Domestic subjects: 22
- Foreign subjects: 78

SOURCE: CRO market outlook; Challenges to FDA’s ability to monitor and inspect foreign clinical trials”, OIG report, June 2010
Companies are seeking to build skills to enter the global biosimilars market

Global biosimilar market is expected to grow rapidly over the next decade

Revenue forecast of biosimilars

In $ billion

<table>
<thead>
<tr>
<th>Year</th>
<th>Other biologics</th>
<th>Monoclonal antibodies</th>
<th>CAGR 2012-20 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>3</td>
<td>4</td>
<td>51</td>
</tr>
<tr>
<td>2016</td>
<td>6</td>
<td>10</td>
<td>+29% p.a.</td>
</tr>
<tr>
<td>2020</td>
<td>15</td>
<td>16</td>
<td>21</td>
</tr>
</tbody>
</table>

SOURCE: Nature Biotechnology; McKinsey analysis
Supply chain has globalized with India and China as major exporters of pharmaceuticals to established markets

Pharmaceutical imports have increased substantially
US pharmaceutical imports, $ billions

<table>
<thead>
<tr>
<th></th>
<th>2000</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finished products</td>
<td>10.6</td>
<td>44.9</td>
</tr>
<tr>
<td>APIs and intermediates</td>
<td>3.5</td>
<td>5.6</td>
</tr>
</tbody>
</table>

Significant shift in manufacturing location to India and China
Country of origin of FDA DMFs

<table>
<thead>
<tr>
<th></th>
<th>2000</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rest of world</td>
<td>91</td>
<td>61</td>
</tr>
<tr>
<td>China</td>
<td>3</td>
<td>31</td>
</tr>
<tr>
<td>India</td>
<td>6</td>
<td>8</td>
</tr>
</tbody>
</table>

SOURCE: Espicom; McKinsey analysis of Drug Master Files on FDA website
Generic manufacturers and contract manufacturers have seen rapid growth in volumes over the past decade

<table>
<thead>
<tr>
<th>Originator drugs</th>
<th>Small molecules</th>
<th>Biologics</th>
<th>Generics</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6</td>
<td>18</td>
<td>13</td>
</tr>
</tbody>
</table>

**Global sales, CAGR, 1999-2008**

<table>
<thead>
<tr>
<th>Region</th>
<th>2001</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>North America</td>
<td>4.5</td>
<td>10.6</td>
</tr>
<tr>
<td>Europe</td>
<td>3.6</td>
<td>7.8</td>
</tr>
<tr>
<td>Asia</td>
<td>1.7</td>
<td>5.7</td>
</tr>
</tbody>
</table>

**Contract manufacturing industry revenue**

SOURCE: Espicom; Evaluate; Datamonitor; Gx Bulletin; McKinsey analysis
Overview of presentation

- Increasing complexity and globalization calls for increased collaboration among regulators

Prioritizing potential areas of collaboration

- Introducing Project RegEx
Key Questions

1. How best to work together?
2. In the context of ongoing initiatives, what should be the additional areas of focus?
3. What should be the priorities and how to drive rapidly in the short-term?
Several lessons can be drawn from private sector collaborations.
Frequent reasons for failure

100% = 149 alliances

- Overambitious – took on too many goals at once
- Unclear definition of and lack of agreement upfront on level of partner commitment needed for success
- Unwieldy governance structure due to high degree of complexity among stakeholder relationships
- Underestimation of technical development requirements (e.g., time, skills)

SOURCE: McKinsey
<table>
<thead>
<tr>
<th>Options for enhancing regulatory cooperation in the globalized environment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Expected impact</strong></td>
</tr>
<tr>
<td>Harmonization and mutual recognition</td>
</tr>
<tr>
<td>Third parties</td>
</tr>
<tr>
<td>Foreign offices</td>
</tr>
<tr>
<td>Partnerships and collaborations</td>
</tr>
<tr>
<td>Benchmarks and best practices</td>
</tr>
</tbody>
</table>
## Options for enhancing regulatory cooperation in the globalized environment

<table>
<thead>
<tr>
<th>Degree of collaboration among regulators</th>
<th>High</th>
<th>Medium</th>
<th>Low</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Immediate</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3-5 years</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Long-Term</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Harmonization/Mutual Recognition**
  - Partnerships and collaborations
  - Third parties

- **Benchmarks and best practice sharing**
  - Foreign offices

**Time to impact**

<table>
<thead>
<tr>
<th>Harmonization/Mutual Recognition</th>
<th>Partnerships and collaborations</th>
<th>Third parties</th>
<th>Foreign offices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3-5 years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Long-Term</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
There are several collaborations underway

<table>
<thead>
<tr>
<th>Existing benchmarking initiatives, e.g.,</th>
<th>Existing regulatory partnerships, e.g.,</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessment of the performance of pre-market evaluation process</td>
<td>Largest international collaboration to share experience, best practices and training for drug inspections</td>
</tr>
<tr>
<td>Assessments of Medicines Regulatory systems in Africa</td>
<td>Collaboration between EMA, FDA and TGA on international GCP and GMP inspection activities launched in September 2009</td>
</tr>
</tbody>
</table>
What could be additional areas of focus?

Management System
- Overarching strategy
- Operating system
- Organization and culture

Main Activities
- Pre-Market Approvals
- Post-Market Surveillance

Public Health Impact
- Prevention
- Improved outcomes
- Public confidence
- Innovation
Prioritizing additional areas of collaboration

Management System

- Overarching strategy
- Operating system
- Organization and culture

Vision and mission
- Policies and standards
- Risk management
- Regulatory science
- International cooperation

Processes
- Quality management system
- Resource management system
- Crisis management system
- Knowledge management system
- Information technology
- Infrastructure and footprint

Organization structure
- Governance and decision-making
- Accountability
- Performance management
- Culture
- Training and professional development
Inspections are a major focus of operational activities and budget for regulators

US FDA FY11 budget request – budget authority and user fees
100% = $3,252 million

Inspections and other field operations
28

Others
72

Inspections are a major area where additional insights are needed

- Large budget and head dedicated to inspections, e.g., for US FDA
  - Over $900 million spent annually on field operations
  - Over 4,000 FTEs on field activities
- Increasing managerial complexity to meet the needs of the globalized supply chain

SOURCE: FDA FY11 budget request
Overview of presentation

- Increasing complexity and globalization calls for increased collaboration among regulators

- Prioritizing potential areas of collaboration

Introducing Project RegEx
Overview of objectives and approach for Project RegEx

Objective

- Identify key differences and best practices in management systems across food and medical products regulators around the world that impact the effectiveness and efficiency of regulatory activities and health outcomes

Approach

- Participants will complete a survey, a brief data request, participate in interviews and share relevant data
- McKinsey will confidentially store the data, conduct analyses and share disguised findings with participants

Our commitment to you

- Assurance by McKinsey of the safety and integrity of the data at all times
- Findings will be de-identified and will only be shared with participants
- In some cases, with approval from participants some high level findings may be published
Initial focus of Project RegEx will be on Inspections

Module 1
- Initial focus on
  - Inspections: GMP, GCP and GLP
  - Products: Drugs, Devices and Food
  - Qualitative and quantitative benchmarks
  - Management best practices

Module 2

Module 3

Module 4 and beyond
Pilot module – What is entailed if you join?

<table>
<thead>
<tr>
<th>Sign up</th>
<th>Input to design (optional - pilot participants only)</th>
<th>Data collection &amp; analysis</th>
<th>Output</th>
</tr>
</thead>
</table>
| • If you have an interest in joining please reach out  
  • Initial discussion with McKinsey  
  • Interest in joining  
  • Sign a confidentiality agreement *(to protect you, and us)*  
  • Nominate point of contact  
  • Nominate individuals to be interviewed for 1 hr | • Review benchmarking design in detail  
  • Share your input for additional questions & data points to collect | • Complete an online survey  
  • Respond to a simple data request  
  • McKinsey conducts 1-hr Interviews with nominated individuals *(in person when possible)*  
  • McKinsey analyzes data collected | • Receive a confidential, customized final report *(your performance relative to de-identified performance of others)*  
  • Meeting to discuss results with McKinsey  
  • Some sanitized excerpts will be published with approval from participants  
  • Provide input to Module 2 *(optional)* |
Survey will be organized by elements of a distinctive management system for regulators – example questions (1/4)

### Elements of a distinctive Management System for Regulators

- **Overarching strategy**
  - Vision and mission
  - **Policies and standards**
    - Risk management
    - Regulatory science
    - International cooperation

- **Operating system**
  - Processes
  - Quality management system
  - Resource management system
  - Crisis management system
  - Knowledge management system
  - Information technology
  - Infrastructure and footprint

- **Organization and culture**
  - Governance and decision-making
  - Accountability
  - Performance management
  - Culture
  - Training and professional development

---

### Project RegEx – Benchmarking Survey

#### Module 1 – Inspections:

- **Policies and standards**

  - What is the **required frequency**, if any, for conducting GMP, GCP and GLP surveillance inspections?

  - What is the difference in frequency between **domestic** and **foreign** inspections?

  - Do you have the **authority** to obtain a product **pedigree** when conducting an inspection?

  - Can you **share** inspection findings with other regulators. If so, what kind?

  - ………
Survey will be organized by elements of a distinctive management system for regulators – example questions (2/4)

Elements of a distinctive Management System for Regulators

▪ Overarching strategy
  – Vision and mission
  – Policies and standards

▪ Risk management
  – Regulatory science
  – International cooperation

▪ Operating system
  – Processes
  – Quality management system
  – Resource management system
  – Crisis management system
  – Knowledge management system
  – Information technology
  – Infrastructure and footprint

▪ Organization and culture
  – Governance and decision-making
  – Accountability
  – Performance management
  – Culture
  – Training and professional development

Project RegEx – Benchmarking Survey
Module 1 – Inspections:

▪ Do you have a root cause analysis of prior compliance issues to best prioritize areas of focus?

▪ What type of models do you to identify prospectively areas of greatest risk to probe? What is the basis for these risk mgmt models?

▪ Do you have a full database of all relevant manufacturing sites domestically and internationally?

▪ ........
Survey will be organized by elements of a distinctive management system for regulators – example questions (3/4)

Elements of a distinctive Management System for Regulators

- **Overarching strategy**
  - Vision and mission
  - Policies and standards
  - Risk management
  - Regulatory science
  - International cooperation

- **Operating system**
  - Processes
    - **Quality management system**
    - Resource management system
    - Crisis management system
    - Knowledge management system
    - Information technology
    - Infrastructure and footprint

- **Organization and culture**
  - Governance and decision-making
  - Accountability
  - Performance management
  - Culture
  - Training and professional development

Project RegEx – Benchmarking Survey Module 1 – Inspections:

- Do you have **quality management systems** in place for inspections? If so, what are the major components of your QMS?

- How do you ensure quality of activities of **third parties and/or contractors**?

- How are you driving implementation of **quality by design** or other similar approaches?

- ……
Survey will be organized by elements of a distinctive management system for regulators – example questions (4/4)

Elements of a distinctive Management System for Regulators

- **Overarching strategy**
  - Vision and mission
  - Policies and standards
  - Risk management
  - Regulatory science
  - International cooperation

- **Operating system**
  - Processes
  - Quality management system

- **Resource management system**
  - Crisis management system
  - Knowledge management system
  - Information technology
  - Infrastructure and footprint

- **Organization and culture**
  - Governance and decision-making
  - Accountability
  - Performance management
  - Culture
  - Training and professional development

**Project RegEx – Benchmarking Survey**

**Module 1 – Inspections:**

- What are the **total numbers of employees** devoted to inspections?
- How many inspections did you conduct in **2010**? Application based? Surveillance?
- How many **domestic and foreign sites** are in your inventory for each type of inspection?
- What is your **current capacity** for inspections?
- Do you have **resource models** given desired workload and utilization levels?
Benchmarking can generate insights that are not possible today and can help guide decision making for senior leaders (1/2)

Hypothetical output – inspections

Number of dedicated pharmaceutical inspectors

<table>
<thead>
<tr>
<th>Agency</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inspector</td>
<td>10</td>
<td>15</td>
<td>22</td>
<td>28</td>
<td>44</td>
<td>51</td>
</tr>
</tbody>
</table>

Average number of years between site inspections – all sites in inventory

<table>
<thead>
<tr>
<th>Agency</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Years</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>6</td>
<td>10</td>
</tr>
</tbody>
</table>

Number of inspections per inspector per year

<table>
<thead>
<tr>
<th>Agency</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inspections</td>
<td>9</td>
<td>10</td>
<td>11</td>
<td>14</td>
<td>15</td>
<td>19</td>
</tr>
</tbody>
</table>

Average number of days on site during inspection

<table>
<thead>
<tr>
<th>Agency</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>
Benchmarking can generate insights that are not possible today and can help guide decision making for senior leaders (2/2)

Hypothetical output - infrastructure and footprint

<table>
<thead>
<tr>
<th>Number of foreign offices</th>
<th>Total staff based in foreign offices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agency 1</td>
<td>0</td>
</tr>
<tr>
<td>Agency 2</td>
<td>1</td>
</tr>
<tr>
<td>Agency 3</td>
<td>1</td>
</tr>
<tr>
<td>Agency 4</td>
<td>2</td>
</tr>
<tr>
<td>Agency 5</td>
<td>3</td>
</tr>
<tr>
<td>Agency 6</td>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of bilateral agreements for inspections</th>
<th>Number of joint inspections conducted with other regulators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agency 1</td>
<td>5</td>
</tr>
<tr>
<td>Agency 2</td>
<td>5</td>
</tr>
<tr>
<td>Agency 3</td>
<td>11</td>
</tr>
<tr>
<td>Agency 4</td>
<td>18</td>
</tr>
<tr>
<td>Agency 5</td>
<td>27</td>
</tr>
<tr>
<td>Agency 6</td>
<td>32</td>
</tr>
</tbody>
</table>

| Agency 1 | 12 |
| Agency 2 | 21 |
| Agency 3 | 22 |
| Agency 4 | 81 |
| Agency 5 | 89 |
| Agency 6 | 241 |
Qualitative insights from benchmarking can help inform management decisions

Potential qualitative insights from Project RegEx

- What is the total size and resource level for your inspection program compared to others?
- Are you inspecting the right subset of firms with the right inspection frequency?
- How does the productivity of your inspectorate compare to others?
- Are you spending enough time on site during the inspection?
- Does your inspectorate have the appropriate level of training and experience?
- Are you collaborating enough with other regulators on inspections?
- How does your use of IT and mobile technologies compare to others?
- How does your performance management process compare to other regulators?

Project RegEx will help regulators form perspectives on the answers to these fundamental questions and many more.
Potential benefits of performance benchmarking

Potential benefits

▪ Lower upfront effort and resources required from participants

▪ Faster time to impact – no pilots or intermediate steps

▪ Easier to scale and achieve truly global insights across participants

▪ Different types of insights – both qualitative and quantitative

▪ Easier to establish performance baseline for quantitative measures
Potential questions for discussion

- How to accelerate this benchmarking effort?
- Who could be the other partners?
- What is most useful and immediately relevant?
- What other areas may be useful to prioritize next?
To learn more about Project RegEx…

1. Contact a McKinsey colleague today at ICDRA pre-conference

Dr. Navjot Singh
Principal
New York

Dr. Imraan Munshi
Associate Principal
Dubai

Dr. Laura Nelson Carney
Associate Principal
Hong Kong

Pritika Prasad
Knowledge Specialist
Zurich

2. Drop your business card in the fishbowl, and we will contact you in the next week

3. Or send an email to:

RegEx@mckinsey.com