



Applying Organization Development tools to build effective External Manufacturing Partnerships in China

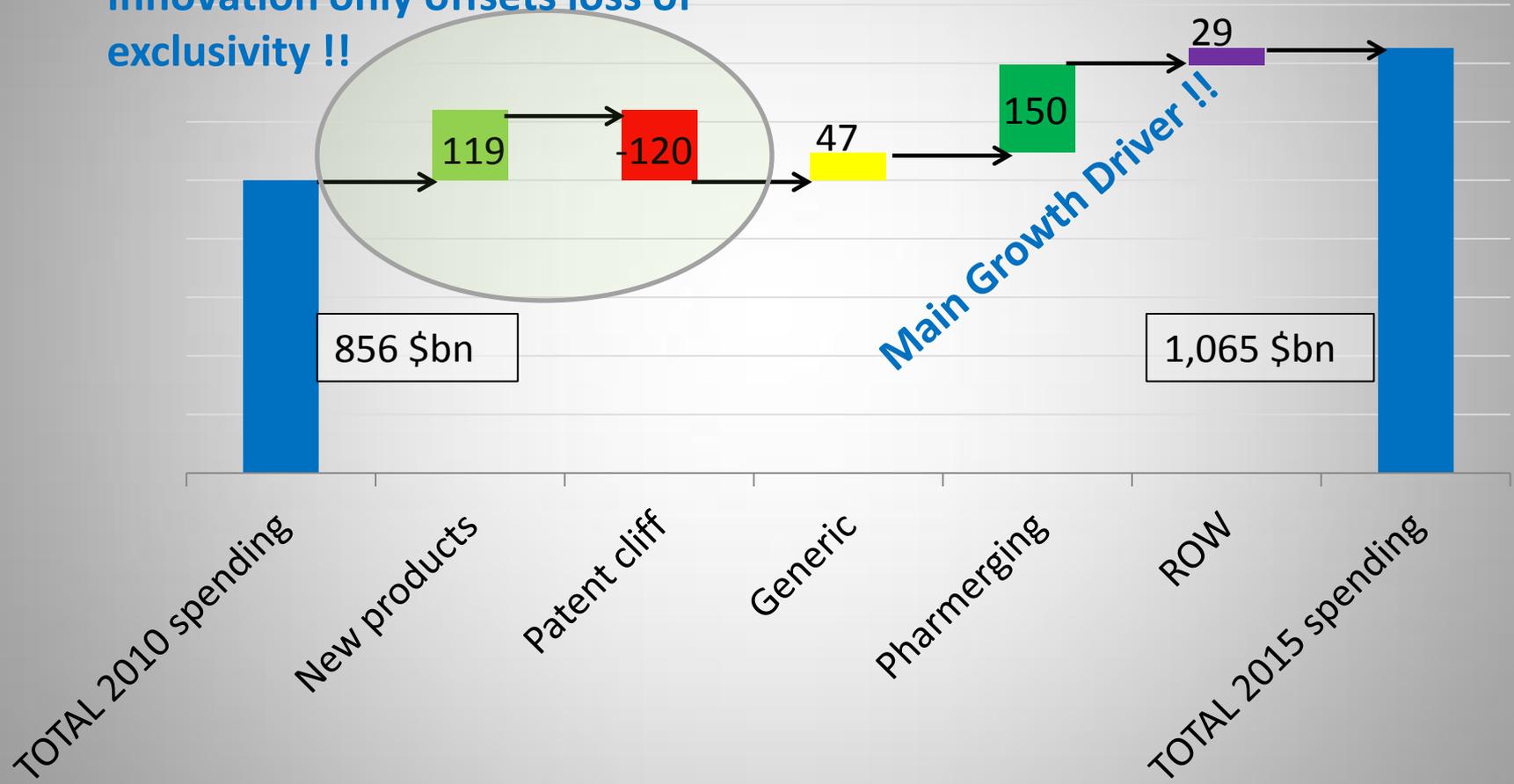
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Overview of Presentation:

- 1. Why ...is this important for Johnson & Johnson?**
 - “Opportunity and Risk Exposure” trade-off
- 2. Whatis the problem we experience?**
 - “Hitting the Wall”
- 3. Which....Organization Development tools do we use?**
 - Matrix of Tools
- 4. Results, impact and lessons so far.....**

Total Pharma industry spending by Category (\$USbn): 2010 - 2015

Innovation only offsets loss of exclusivity !!



Main Growth Driver !!

.... and China remains the dominant market opportunity in terms of both size and growth

1. Total market spend in China versus all other markets (*CAGR: 2010-15*)

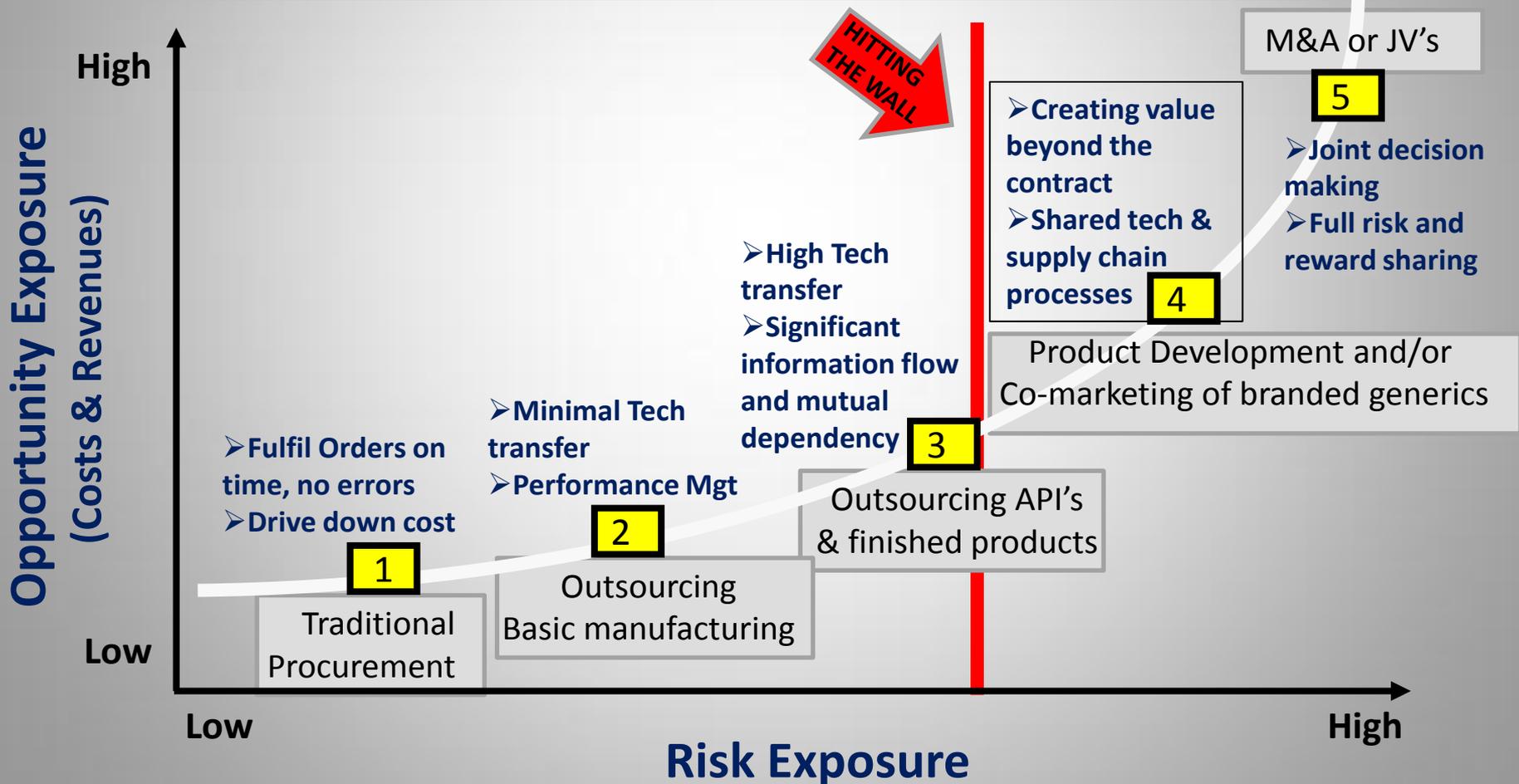
- **GAGR 2010-2015: US + EU5 = 0-3% China = 19-22%**
- Total Spend 2010: US+EU5 = 53% . “Pharmerging” = 17% -> of which China = 4.5%
- Total Spend 2015: US+EU5 = 43% . “Pharmerging” = 28% -> of which China = 11%

2. Global Market sizes (% Total: *2010 versus 2015*)

	<u>2010</u>	<u>2015</u>
US	36%	30%
EU5	17%	13%
Japan	11%	11%
China	4.5%	11%

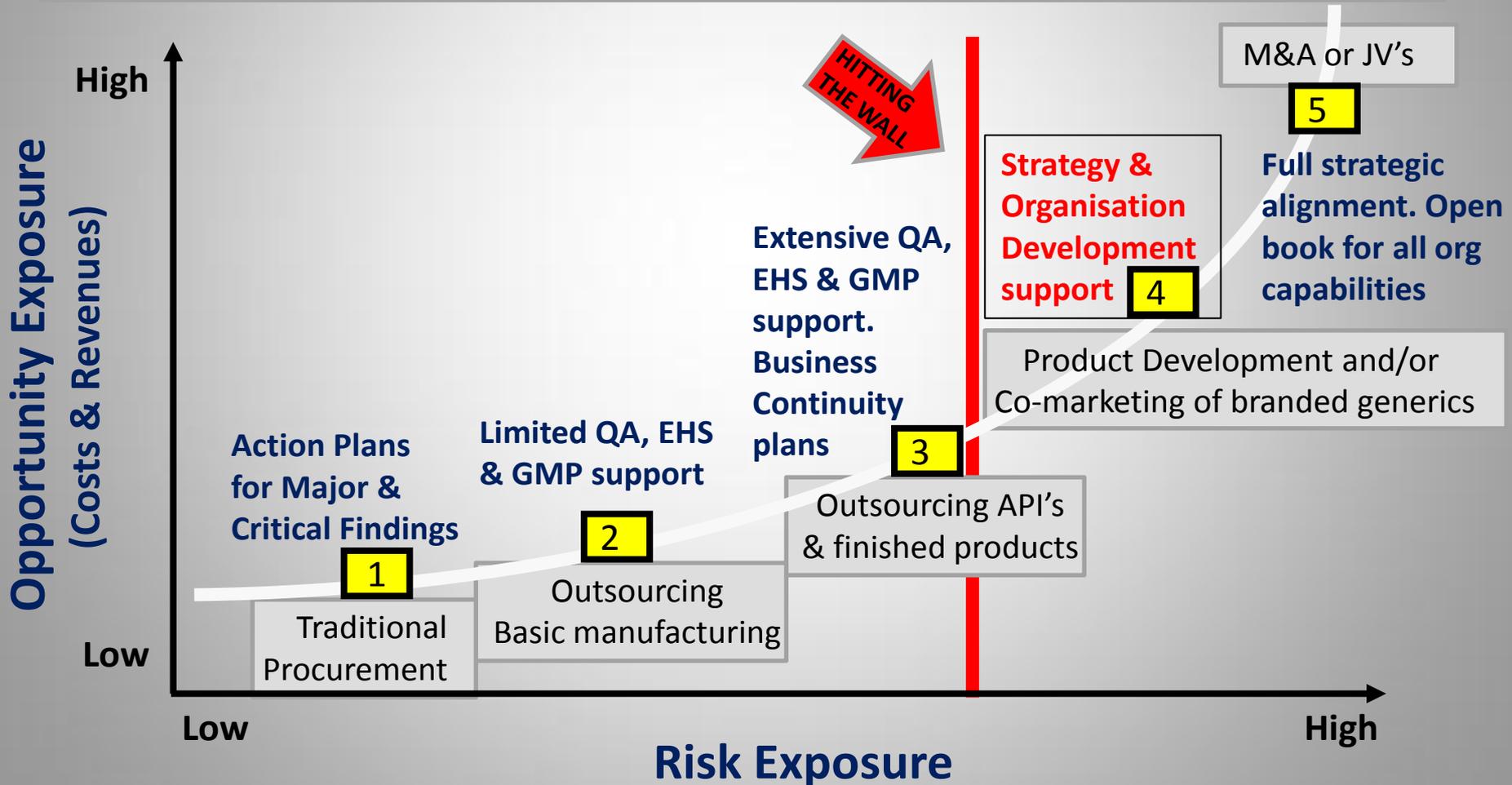
“Risk Exposure” versus “Opportunity Exposure”

A trade-off exists depending on how much Big Pharma wishes to exploit these growth opportunities in China. And these trade-offs imply different types of Partnerships with different characteristics...



“Risk Exposure” versus “Opportunity Exposure”

...and J&J’s experience suggests higher level Partnerships require Organisation Development support as well as GMP, QA & EHS support



But few Chinese API Partners currently seem able to take advantage of this opportunity

1. Only **5%** of the SFDA Qualified API mfg's are also FDA Qualified API manufacturers
 - Huge gap between current API manufacturer capability and global expectations
2. Only **15%** of FDA audits in China 2011 were successfully passed
 - Passing FDA inspections is NOT only about technicalities; it's increasingly about having robust **organizational** processes
3. China more and more under the spotlight: average yearly number of Chinese API manufacturers inspected by FDA: 2001-2008=10/year. 2009 = 35
 - No longer possible to ignore the international requirement
4. March, 2011: New "Good Manufacturing Practice" in force (Ministry of Health, PRC)
 - SFDA requirements are brought more in line with FDA expectations

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J&J experience in partnership with Chinese companies

- ❑ Despite extensive research, J&J finds it very difficult to identify suitable partners “ready-now” to initiate partnership programs
- ❑ Western approach on quality/EHS is only recently introduced in China
- ❑ Most companies focus on short-term improvements in the technical fields and plant expansion
- ❑ Partners are willing to improve their capabilities, but need extensive and continuous support → not self-sustainable

The typical situation ...

- ❑ Energized companies with a lot of vision, but in need of guidance
- ❑ Willing to invest, but focus on standard capacity expansion...
- ❑ Can grow faster initially, but they inevitably arrive at the moment when, without organizational and management capabilities, progress is no possible anymore
→ they “hit the wall”

Explaining the idea of “Hitting The Wall”

Technical Areas where we experience this problem:

- Technology transfer
- Quality / compliance
- EHS
- Supply chain

The issue:

- One-way giving
- **Process & technical knowledge is passively accepted** by the EM organisation, as is. There is limited deep understanding of the content and the essence of the underlying knowledge.
- This results in the EM organization being unable to **proactively translate the knowledge into sustainable and autonomous action.**
- This also results in **very limited systematic cascading of the knowledge** into all levels and department in the EM organisation.

The consequence:

1. No evolution of the EM
2. Heavy and ongoing support for the EM from the Big Pharma Partner
3. **Impossible to “create value beyond the contract”**

In J&J’s experience the way to progress to “higher level” Partnerships is to develop the EM’s Strategy & Organization capabilities, and not only focus on technical capabilities

Why do we experience “Hitting The Wall”?

Potential Root Causes for the existence of “The Wall” phenomenon:

1. Limited experience of analysing existing or expected technical & organisational capabilities within a broader external environment and business strategy context
2. Limited experience and understanding of how to apply new technical know-how and translate into customised capabilities & individual competencies
3. Limited history, and therefore culture, of autonomous self-improvement and self-sufficiency – both in relation to the Customer/Partner’s expectations as well as own employees abilities
4. Understanding and applying new concepts. Some management concepts simply don’t exist because experience has not previously created a need – and therefore the language to explain the concept doesn’t exist.
5. Mutual trust and respect is often limited by the implicit nature of traditional outsourcing and procurement driven relationships. Moving higher on the “risk versus opportunity” curve requires a significant change in attitude and behaviour from both parties.

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History and Context

- Since the '80's J&J has outsourced to China, providing support in the areas of manufacturing, quality and compliance
- In the mid 2000's, J&J introduced EHS and Business Conduct audits and training
- More recently a strategic push to rationalise the supplier base, and differentiate them into tiers (end of 2000's)
- In 2007 we introduced a formal "J&J Asks for Feedback" process in China and India
- In 2008 we initiated the "Organisation Assessment" process in China & India
- In 2010 and 2011 J&J developed and deployed additional Strategy and Capability Assessment processes for Tier 1 EM's in China
- In 2012 we shall pilot additional Organisation Development tools and processes with more strategic partners in China and India

What OD tools and processes do we use?

OD Tools & Processes:

1. **J&J Asks for Feedback (2007):** Designed to capture concrete areas of improvement but also to build a better “horizontal communication” attitude with EM Partners
2. **OD Self-Assessment (2008):** A detailed review of Partner’s Organisational Maturity in following areas, built round a 2 day off-site with 15-30 executives & managers:
 - Strategic Leadership
 - Communications Effectiveness
 - Organisation & People Development
 - Financial Health
3. **Capabilities Assessment (2011):** A detailed review of the technical and organisational capabilities of Partner, including technology & process capabilities across the value chain.
4. **Strategy and Communications Review (2011):** Involves both parties formulating and sharing their respective 2-3 year strategic direction and current position. Emphasis on better understanding respective opportunities for deeper collaboration.
5. **Employee Survey in Partner organisation (2011):** Data linked to OD Assessment process
6. **Competency Assessment Model (2012):** To bridge gap between Capabilities Assessment and EM employee development needs.

Matrix of Development Areas and OD Tools in use today:

Development Areas / Tools	OD Assessment	Employee Survey	Strategy Workshop	Capabilities Analysis	J&J Asks for Feedback	Competency Model
Strategic Leadership	YES	YES	YES	YES	YES	YES
Communications Effectiveness	YES	YES	YES	YES	YES	YES
Organisation & People Development	YES	YES (partially)	YES (partially)	YES	NO	YES
Financial Health	YES	NO	YES	NO (but could)	NO	YES (partially)
<i>Other Technical Domains (QA, EHS, GMP)</i>	NO	YES	YES (Partially)	YES	YES	YES

A closer look at these 6 OD Tools:

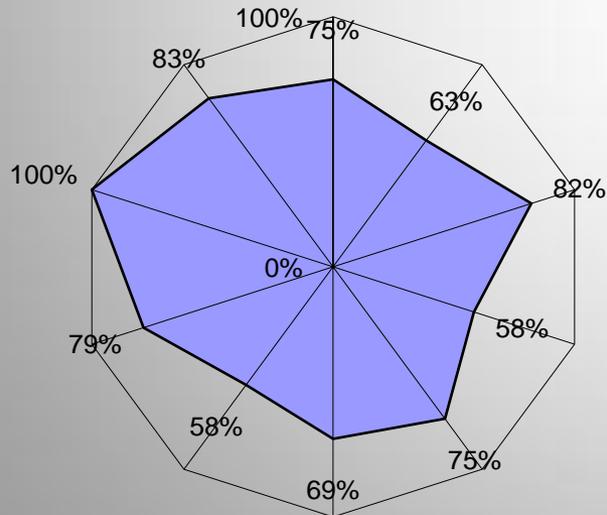
- 1. Organization Development (OD) Assessment**
- 2. Capabilities Assessment**
- 3. Competency Assessment**
- 4. Strategy Analysis and Alignment**
- 5. Employee Survey**
- 6. Johnson & Johnson Asks for Feedback**

The OD Assessment Tool measures performance across 10 areas in 4 categories and is repeated every 2-3 years

The below illustrates the evolution of a Chinese FDA approved API manufacturer between end 2008 and early 2011. The development path was very positive!

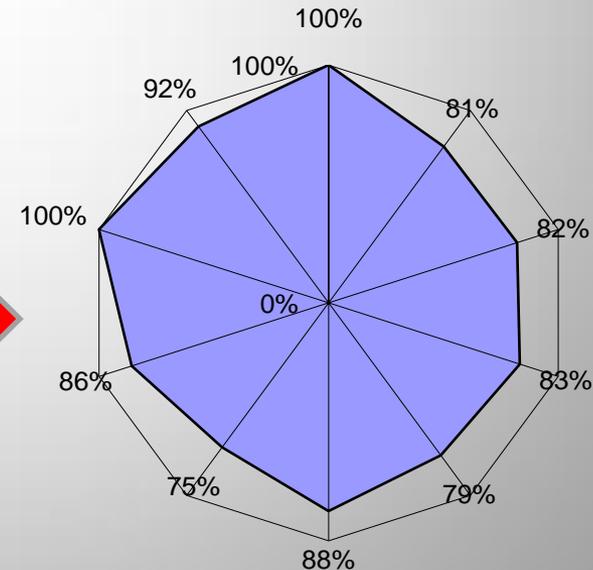
2008 Results summary:

- Weakness in all Categories except Financial Health
- Specific weakness in Organization Alignment (63%)
Communications Ability (58%) & Capability Development (58%)



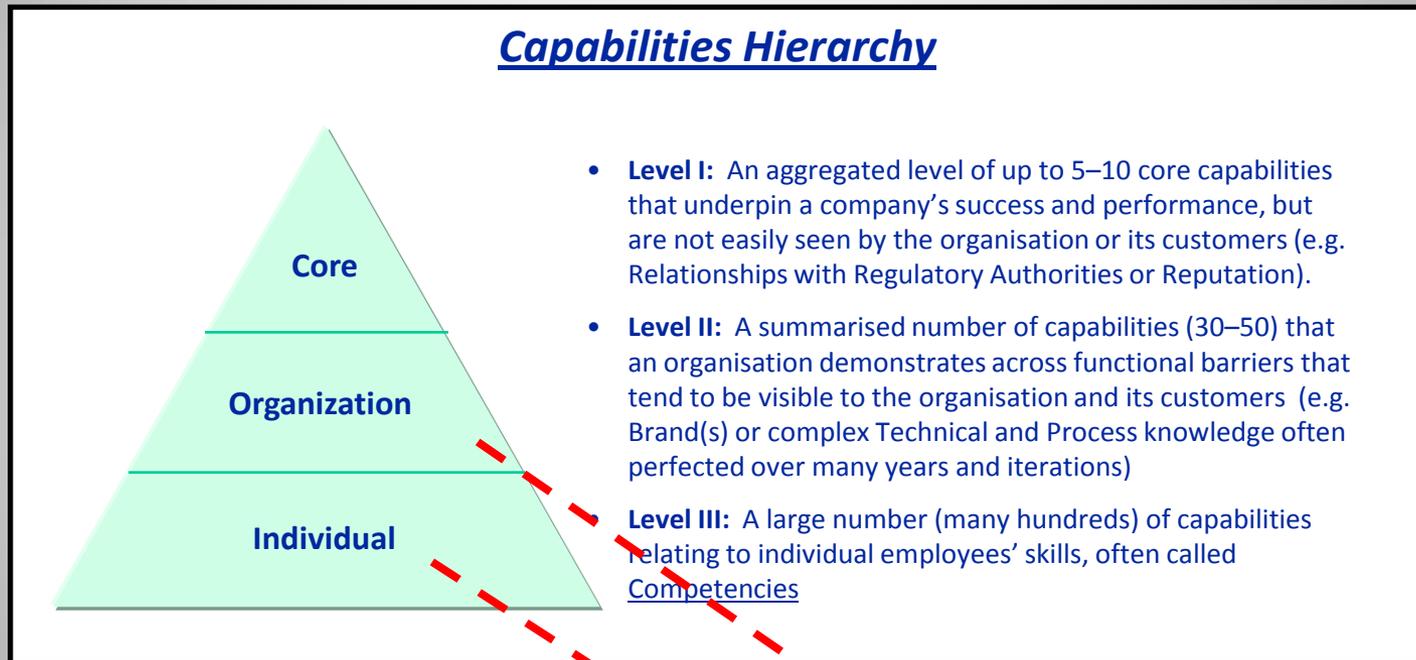
2011 Results summary:

- Improvement in all areas!
- Weakest areas remain Capability Development (75%) and Organisation Alignment (81%)



Capabilities exist in different forms within organizations

Different tools are therefore required for different types of organizational analysis...



- For Strategy analysis we focus on organizational capabilities
- For Competency analysis we focus on individual capabilities

The Organisational Capabilities Assessment tool has also been successfully used with FDA audited Partners in China

Value Chain Capability Areas:

1. Pre-starting material
2. Intermediates
3. Legacy API's
4. High value, proprietary API's

Cross functional Capability Areas:

1. Technical Levels 1-3
2. Services
3. Organisation & Leadership
4. Compliance

This analysis was used to identify important technology and capability gaps relative to these partners' 3 year strategic objectives.

CAPABILITY MAPPING ACROSS THE API VALUE CHAIN				
PRODUCT & SERVICE AREAS	Pre-starting Material	Intermediate Building Blocks	Legacy API (high volume, off patent)	High-Value API (Proprietary API,)
CAPABILITY DOMAINS				
Technical Level 1				
tech transfer				
chemical manufacturing				
GMP manufacturing	N/A			
API Suites	N/A	N/A		
Powder Handling				
Technical Level 2				
small and large volumes / portfolio of products				
high potent				
hydrogenation				
special chemistry (bromination, ...)			N/A	N/A
cryogenation capabilities			N/A	N/A
Technical Level 3				
synthesis development				
process development				
pilot plant scale up				
analytical development				
clinical batches	N/A	N/A		
unique capabilities (continuous reactor, ...)				
Services				
packing and distribution services				
analytical testing services				
safety testing				
solvent recovery units				
cold storage				
Organisation & Leadership				
Strategy Formulation				
Strategy Deployment & Communication				
Communication Effectiveness with J&J				
Talent Management				
Talent Development				
High Performing Culture				
Financial Management				
Business and Ethical Conduct				
Compliance				
QA / ISO				
QA / ICH Q7A				
QA / FDA/EMA/WHO approved	N/A			
EHS / ML 1-2				
EHS / ML 3-4				
EHS / ML 5-6				
EHS / ISO				
Legal Compliance				
Other Capability Areas?				

Individual Capabilities are assessed and analysed with the use of a Competency Model.

The benefits for both parties are summarised below

	For Johnson & Johnson	For Chinese EM Partners
For the Organisation	<ul style="list-style-type: none"> • Provides a practical bridge between identifying strategic capability gaps & implementing missing individual competencies • Reduces Compliance & Business Risk • Builds EM Partner self-sufficiency & autonomy 	<ul style="list-style-type: none"> • Aligns individual employees' skills, knowledge & behaviour with organisation's strategy and market environment. • Provides tool for objective assessment & development
For Managers	<ul style="list-style-type: none"> • Provides objective criteria for influencing EM Partner talent development plans 	<ul style="list-style-type: none"> • Provides objective hiring & recruitment criteria • Sets objective standards for roles and job descriptions • Provides guidelines for employee assessment and development plans
For Employees	<i>Not Applicable</i>	<ul style="list-style-type: none"> • Clarifies standards & expectations • Provides an objective basis for identifying & planning personal development actions

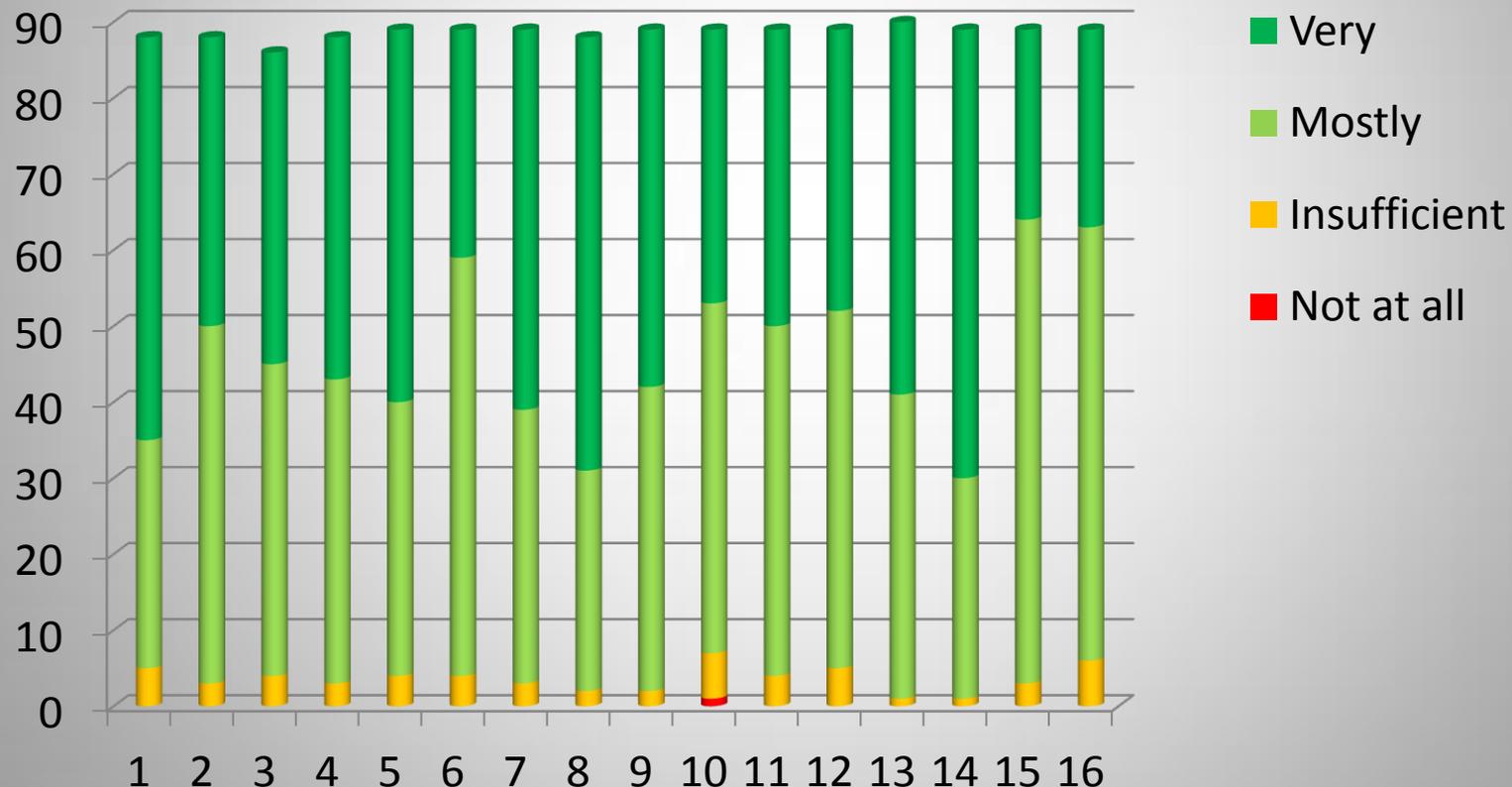
The Strategy Alignment process is important for both parties to identify future business opportunities.

Standard tools (e.g. TOWS analysis below) and structured dialogue are a critical enabler of this



Well designed Employee Surveys inside the Partner organization are a valuable tool for generating data

This data is used to help validate the results from some of the other Assessment Tools:



Finally, we employ a J&J Asks for Feedback process

- To understand and listen closely to our Partners issues, concerns and needs
- To understand how we are perceived and performing relative to our Partners' needs
- To identify actions or necessary conversations before minor misunderstandings grow into bigger relationship problems

How do both parties apply these tools and expertise?

1. Establish trust and strong mutual respect:

- Sincerity in use of word “Partnership” (Actions consistent with this)
- Allow feedback and survey data to be shared
- Encourage high levels of bottom up employee participation in OD workshops

2. Introduce the OD tools in a deliberate and customised sequence:

- Depending on needs and organizational readiness of the partner
- Cumulative deployment over several annual cycles

3. Good preparation and skilful design of workshops and other structured interventions:

- High involvement of representatives from both parties, including senior management time
- Use a skilled advisor & facilitator who is trusted by both parties

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Results, impact and lessons learned

1. Cost, productivity, cost avoidance for Big Pharma

- Less intensive man hours of support to achieve same results
- Lower risk of interruption to the supply chain
- Quicker time-to-market (worth 1-2 years of “patented” market)
- Less expensive contingency plans (i.e. no need to transfer the process to an additional alternative supplier).
- Value creation beyond contract value.

2. Quicker and more efficient progresses in technical domains

- Process optimization
- Capacity expansion (engineering, EHS, compliance)
- New technologies implementation

3. More opportunities for our Chinese Partners

- Organic and self-sustainable growth for the company
- Access to partnership with Global companies
- Direct access to Western markets
- Creation of the background needed to be “FDA-approvable”

Testimonials from Chinese Partners validate the effectiveness of these OD tools

The OD Assessment tool *helped us develop a deep understanding of the key drivers and capabilities that sit behind high performing organisations in a very concrete and practical way*” CEO of major Chinese CMO – August 2011

The Strategy and Capability Assessment tools *helped me to analyse, formulate and communicate my strategy position, and underlying capabilities, to a group of senior executives from one of our biggest customers*” CEO of major Chinese CMO – August 2011

The first OD Assessment *clarified for us very well in which areas we had strengths and weaknesses, and the actions we needed to take to improve*” CEO of major Chinese API supplier – February 2012

By taking the OD Assessment 2.5 years later *we realised just how valuable it had been to take the previous one and to see in which area we had improved. It was also very valuable to invite some of our younger managers to learn by participating in the 2 day workshop*” CEO of major Chinese API supplier – February 2012

Thank you!

Adam Pharaoh

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