Emerging Issues in the Life Science Industry

Marsh 2005 Life Science Conference

„Effective Risk Management Solutions for the Life Science Industry“

20 & 21 October 2005, Berlin
Agenda

• Life Science Industry – a global overview
  • Markets and Geographies
  • Industry Issues

• Emerging Health Markets
  • Market Drivers and Industry Positioning
  • Therapeutic Areas

• Convergence of Life Science industry segments
  • Innovation Driver
  • Impact of Biotechnology
  • Deals

• Regulation and Risk
  • Transparency
  • Integrity
  • Value

• Ernst & Young – Advisor in the Life Science industry
  • Pharma-, Biotech-, Health Care Reports
  • Ernst & Young Risk Advisory Service
Life Science Industry – a global overview

Pharma – the global market

Global sales $550bn

North America 45%
European Union 26%
Rest of Europe 7%
Latin America 3%
Japan 11%
Asia (excl. Japan & China), Africa and Australia 6%
China 2%

Source: IMS Health MIDAS MAT Dec 2004

Market Size
Growth Rate

US$ (bn)

% Growth

US$

0 2 4 6 8 10 12 14

Pharma – the global players

Top 10 Pharmaceutical Companies, Locations

- Pfizer
- Bristol-Myers Squibb
- Johnson & Johnson
- Merck
- GlaxoSmithKline
- AstraZeneca
- Sanofi-Aventis
- Roche
- Novartis
- Abbott
Life Science Industry – a global overview

Pharma – growth/growth mix differs

NA

7.8%
12%
47%

Growth 2003-04
CAGR 2000-04
Share of Globe

Europe

6.7%
9.2%
31%

Growth 2003-04
CAGR 2000-04
Share of Globe

LA

13%
3%
4%

AAA

13%
11%
7.6%

Source: IMS MIDAS MAT/12 2004
### Pharma – the patent expiry dilemma

<table>
<thead>
<tr>
<th>Company</th>
<th>Sales US 2004 ($M)</th>
<th>Major expiry year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zocor</td>
<td>Merck</td>
<td>3163</td>
</tr>
<tr>
<td>Zoloft</td>
<td>Pfizer</td>
<td>2656</td>
</tr>
<tr>
<td>Pravachol</td>
<td>BMS</td>
<td>1420</td>
</tr>
<tr>
<td>Zofran</td>
<td>GSK</td>
<td>1035</td>
</tr>
<tr>
<td>Ambien</td>
<td>Sanofi-Aventis</td>
<td>1489</td>
</tr>
<tr>
<td>Lamisil</td>
<td>Novartis</td>
<td>528</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>10741</strong></td>
</tr>
<tr>
<td>Coreg</td>
<td>GSK</td>
<td>779</td>
</tr>
<tr>
<td>Seloken/Toprol</td>
<td>AstraZeneca</td>
<td>977</td>
</tr>
<tr>
<td>Risperidone</td>
<td>J&amp;J</td>
<td>1711</td>
</tr>
<tr>
<td>Zyrtec</td>
<td>Pfizer</td>
<td>1287</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>6745</strong></td>
</tr>
</tbody>
</table>
Pharma – the generic competition

- Generic substitution - central policies for healthcare cost containment.
- Factors contributing to the growth of the generic industry include:
  - Legislation supporting increased use of generics
  - Expiration of blockbusters coming off patent
  - Successful patent challenges
  - Intense commitment to growth from generics manufacturers
  - Support from payers for generic alternatives to brand name drugs through formulary development and promotion

**Generic market share in different geographic areas (2004)**

<table>
<thead>
<tr>
<th>Country</th>
<th>Large generic markets</th>
<th></th>
<th>Limited generic markets</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% Generics by volume</td>
<td>% Generics by value</td>
<td>% Generics by volume</td>
<td>% Generics by value</td>
</tr>
<tr>
<td>US</td>
<td>56</td>
<td>17</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Germany</td>
<td>41</td>
<td>23</td>
<td>16</td>
<td>5</td>
</tr>
<tr>
<td>UK</td>
<td>55</td>
<td>24</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Spain</td>
<td>7</td>
<td>5</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>Japan</td>
<td>16</td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Italy</td>
<td>4</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>France</td>
<td>10</td>
<td>7</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: IMS, European Generic Medicines Association
Life Science Industry – a global overview

Pharma – the innovation deficit dilemma

Cost / benefit ratio

Time to approval

New drugs approved

Global R&D expenditure ($m)

Year

1960s 1970s 1980s 1990s

Preclinical phase  Clinical phase  Approval phase

2.4 4.4 2.8 1.8

2.5 5.1 5.9 6.1

2.1 6.3

5

10

15

20

25

30

35

40

45

R&D spend

0

10

20

30

40

50

60

Pharma – the innovation deficit dilemma and the biotech promise

Biotech and big pharma R&D expenditures and FDA new molecular entity (NME) approvals

Biotech R&D expenditures include large acquired in-process R&D charges resulting from mergers in some years.

Approvals include only new molecular entities, and exclude label approvals, new formulations and combinations. Certain drugs partnered between biotech and big pharma companies are counted in both groups. Big pharma is defined as the 20 largest global pharmaceutical companies by market cap. Companies that do not meet the definition of big pharma and do not meet Ernst & Young's definition of biotechnology are excluded from the analysis. Biotech R&D expenditures include large acquired in-process R&D charges resulting from mergers in some years.

Source: Ernst & Young
## Biotech is catching up

<table>
<thead>
<tr>
<th>Company</th>
<th>1995</th>
<th>2000</th>
<th>2005 (May 10th)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Merck</td>
<td>$37.4</td>
<td>$146.5</td>
<td>$75.0</td>
</tr>
<tr>
<td>Pfizer</td>
<td>$19.3</td>
<td>$252.8</td>
<td>$204.5</td>
</tr>
<tr>
<td>Biotech Industry</td>
<td>$41.0</td>
<td>$330.8</td>
<td>$358.0</td>
</tr>
<tr>
<td>Amgen</td>
<td>$5.7</td>
<td>$63.2</td>
<td>$72.7</td>
</tr>
<tr>
<td>Genentech</td>
<td>$5.7</td>
<td>$29.0</td>
<td>$73.5</td>
</tr>
</tbody>
</table>

**Source:** Ernst & Young
**Biotech is catching up**

<table>
<thead>
<tr>
<th>Top therapeutic companies by market cap (in $ billions)</th>
<th>Top therapeutic companies by revenues (in $ billions)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pharma</strong></td>
<td><strong>Biotech</strong></td>
</tr>
<tr>
<td>Johnson &amp; Johnson</td>
<td>Genentech</td>
</tr>
<tr>
<td>Pfizer Inc.</td>
<td>Amgen</td>
</tr>
<tr>
<td>GlaxoSmithKline plc (ADR)</td>
<td></td>
</tr>
<tr>
<td>Novartis AG (ADR)</td>
<td></td>
</tr>
<tr>
<td>Roche Holding Ltd. (ADR)</td>
<td></td>
</tr>
<tr>
<td>Abbott Laboratories</td>
<td></td>
</tr>
<tr>
<td>Merck &amp; Co., Inc.</td>
<td></td>
</tr>
</tbody>
</table>

*Source: Ernst & Young; Yahoo Finance*
Biotech is catching up with the US dominating

USA

EU

Asia-Pacific

(public companies)

No. Comp.  Mrd. US$

US

EU

D  UK  F  CH

No. Comp.  Mrd. US$

(Mrd. US$)
Life Science Industry – a global overview

Biotech is catching up in Asia-Pacific

Asian governments: strategic investments, ambitious goals

- **Japan**: $200B
- **Korea**: Global ranking of 7th by 2012
- **Taiwan**: Invest $4.5 B; 18
- **Malaysia**: One of five core technologies
- **New Zealand**: $660M industry in next decade, with 18,000 employees

**India** (Draft policy): $5B industry by 2010

Biotech is catching up in Asia-Pacific
Emerging Health Markets

Emerging Trends for the Health Market of the Future

Demographics/ Ageing Population - Disease Spectrum change

- Age-related and degenerative Diseases
  - Neurology / Stroke
  - Cancer
  - Orthopedics

- Lifestyle-related Diseases
  - Metabolic Diseases
    - Obesity-related diseases
  - Infectious Diseases

Individualised Health Planning - Customer Patient

- Prevention
- Personalised Medicine
- Private Health Plans
  - Health Supplements
  - Self medication/OTC

Information-based Medicine

- Multimorbidity and Comprehensive Care - Innovative Treatment Concepts

- Interdisciplinary Therapy
  - interlinking diagnosis - therapy
  - interlinked high tech medicine
  - interlinking patient – therapy - care

- Managed Care
Emerging Markets – Health Care

Health Market as a significant economic factor in the future

Life Science Industry
„Preventing, detecting, treating diseases“

Food and Health Supplement Industry
„Supporting health“

- Evidence-based and „Personalized“ Medicine
  - Innovative Therapies
  - Innovative Diagnostics
  - Innovative Medical Devices
- Prevention Medicine
- Convergence of Disciplines
  - Theranostics
  - Molecular Imaging
  - Drug–coated Devices

Health IT

- Physician Care (amb. u. stat.)
- Care / Rehabilitation
- Fitness / Wellness

Health Care
„Services within the Health Market“

- Nutrition /Neutraceuticals
- Life Style-Products
- Fitness-/Wellness-Products
Emerging Markets – Health Care

Leading Therapy Classes in 2004 ($bn)…

<table>
<thead>
<tr>
<th>Therapy Class</th>
<th>1995</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statines</td>
<td>4</td>
<td>25</td>
</tr>
<tr>
<td>Anti-cancer</td>
<td>4,5</td>
<td>26</td>
</tr>
<tr>
<td>EPO</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>Anti-psychotics</td>
<td>0,5</td>
<td>7</td>
</tr>
<tr>
<td>Biphosphonates</td>
<td>0</td>
<td>4,5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>11</td>
<td>72,5</td>
</tr>
</tbody>
</table>

Source: Mintel
Emerging Markets – Health Care

...and biotech pipelines address medical needs with preference

365 Phase III clinical products

- Miscellaneous 25%
- Cancer 28%
- Cardiovascular 12%
- Infectious Diseases 16%
- Central Nervous System 12%
- Autoimmune 5%
- Diabetes 2%

DIAGRAM: Pie chart with percentages for various medical conditions.
Convergence of Life Sciences

Life Science Network as future innovation driver

Innovations from interfaces
### Impact of Biotechnology

- **Biologicals**
  - therapeutic proteins
  - antibodies
  - peptides
  - biogenerics
- **Molecular Diagnostics**
  - gene testing
  - disease markers
  - theranostics
  - personalized medicine
- **Cell Biology**
  - Stem cells
  - vaccines
  - tissue engineering
- **Nanobiotech**
  - biotech/devices

#### Top biological therapeutics

<table>
<thead>
<tr>
<th>Product</th>
<th>Type</th>
<th>2004 Sales, $M</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Procrit</td>
<td>Recombinant erythropoietin</td>
<td>$3,589</td>
</tr>
<tr>
<td>2. Rituxan</td>
<td>Chimeric monoclonal antibody, anti-CD20</td>
<td>$2,963</td>
</tr>
<tr>
<td>3. Remicade</td>
<td>Chimeric monoclonal antibody, anti-TNF-alpha</td>
<td>$2,891</td>
</tr>
<tr>
<td>4. Epogen</td>
<td>Recombinant erythropoietin</td>
<td>$2,600</td>
</tr>
<tr>
<td>5. Enbrel</td>
<td>Recombinant fusion protein, soluble TNF receptor linked to IgG1</td>
<td>$2,580</td>
</tr>
<tr>
<td>6. Aranesp</td>
<td>Novel erythropoiesis-stimulating protein (2nd generation EPO)</td>
<td>$2,500</td>
</tr>
<tr>
<td>7. Epogen/NeoRecormon</td>
<td>Recombinant erythropoietin</td>
<td>$1,826</td>
</tr>
<tr>
<td>8. Neulasta</td>
<td>Pegylated version of Neupogen</td>
<td>$1,700</td>
</tr>
<tr>
<td>9. Avonex</td>
<td>Recombinant interferon beta-1a</td>
<td>$1,417</td>
</tr>
<tr>
<td>10. Pegasys/Copegus</td>
<td>Recombinant interferon alpha-2a modified with PEG (monotherapy, also in combination with Copegus [ribavirin])</td>
<td>$1,370</td>
</tr>
</tbody>
</table>
# Convergence of Life Sciences

## Consolidation through alliances and M&A

### Pharma M&As in 2004

<table>
<thead>
<tr>
<th>Year</th>
<th>Purchaser</th>
<th>Target</th>
<th>Cost of target ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005*</td>
<td>Sanofi</td>
<td>Daichi</td>
<td>7.7</td>
</tr>
<tr>
<td>2005*</td>
<td>Daiichi Seiyaku</td>
<td>Sumitomo</td>
<td>2.1</td>
</tr>
<tr>
<td>2005</td>
<td>Yamanouchi</td>
<td>Fujisawa</td>
<td>6.9</td>
</tr>
<tr>
<td>2004</td>
<td>Sanofi-Synthelabo</td>
<td>Aventis</td>
<td>7.2</td>
</tr>
<tr>
<td>2004</td>
<td>UCB</td>
<td>Celtech</td>
<td>2.4</td>
</tr>
<tr>
<td>2003</td>
<td>Pfizer</td>
<td>Pharmacia</td>
<td>6.3</td>
</tr>
<tr>
<td>2002</td>
<td>Amgen</td>
<td>Immunex</td>
<td>17.5</td>
</tr>
<tr>
<td>2001</td>
<td>Bristol-Myers</td>
<td>DuPont Pharma</td>
<td>7.8</td>
</tr>
<tr>
<td>2000</td>
<td>Johnson &amp; Johnson</td>
<td>Alza</td>
<td>11.7</td>
</tr>
<tr>
<td>2000</td>
<td>Shire</td>
<td>Biogen Xénovis</td>
<td>9.5</td>
</tr>
<tr>
<td>2000</td>
<td>ABBott</td>
<td>Knoll (BASF Pharma)</td>
<td>7.0</td>
</tr>
<tr>
<td>2000</td>
<td>Glaxo Wellcome</td>
<td>SmithKline Beecham</td>
<td>72.4</td>
</tr>
<tr>
<td>2000</td>
<td>Pfizer</td>
<td>Werner-Lambert</td>
<td>87.3</td>
</tr>
<tr>
<td>1999</td>
<td>Pharmacia Upjohn</td>
<td>Monsanto</td>
<td>28.9</td>
</tr>
<tr>
<td>1999</td>
<td>Rhone-Poulenc Rorer</td>
<td>Hoechst AG</td>
<td>21.2</td>
</tr>
<tr>
<td>1999</td>
<td>Sanofi</td>
<td>Syntelabo</td>
<td>9.2</td>
</tr>
<tr>
<td>1998</td>
<td>Zeneca</td>
<td>Astra</td>
<td>34.8</td>
</tr>
<tr>
<td>1998</td>
<td>Hoffmann-La Roche</td>
<td>Boehringer Mannheim</td>
<td>11.0</td>
</tr>
<tr>
<td>1998</td>
<td>Sanofi</td>
<td>Zambon</td>
<td>600.0***</td>
</tr>
<tr>
<td>1998</td>
<td>Glaxo</td>
<td>Burroughs Wellcome</td>
<td>30.0</td>
</tr>
<tr>
<td>1998</td>
<td>Hoechst-Poussiel</td>
<td>Marion Merrell Dow</td>
<td>7.1</td>
</tr>
<tr>
<td>1998</td>
<td>Pharmacia Upjohn</td>
<td>12.0***</td>
<td></td>
</tr>
<tr>
<td>1998</td>
<td>Rhone-Poulenc Rorer</td>
<td>Fisons</td>
<td>2.7</td>
</tr>
<tr>
<td>1998</td>
<td>American Home</td>
<td>American Cyanamid</td>
<td>8.2</td>
</tr>
<tr>
<td>1994</td>
<td>Hoffmann-La Roche</td>
<td>Syntelabo</td>
<td>5.3</td>
</tr>
<tr>
<td>1994</td>
<td>Sanofi</td>
<td>Sterling</td>
<td>1.0</td>
</tr>
<tr>
<td>1990</td>
<td>Beecham</td>
<td>SmithKline Beckman</td>
<td>0.5***</td>
</tr>
</tbody>
</table>

*Source: Deutsche Bank, Bloomberg.  **Preliminary.  ***Value of merged entity.
Convergence of Life Sciences

Consolidation through alliances and M&A

Beyond geographic borders: 2004 biotech-biotech and biotech-pharma cross-border alliances

Europe 50%  Americas 41%  Asia-Pacific 10%

Source: Ernst & Young and Deloitte
Distribution reflects 630 cross-border alliances
Numbers may appear inconsistent because of rounding

- U.S.: 237
- Canada: 63
- UK: 105
- Germany: 103
- Switzerland: 70
- France: 48
- Denmark: 25
- Sweden: 23
- Netherlands: 23
- Australia: 21
- Japan: 57
- Israel: 9
- Ireland: 11
- Italy: 14
- Belgium: 16
- China: 5
- India: 4
- Singapore: 3
- Korea: 2
- Cuba: 1
- Tunisia: 1

Finland: 7
Norway: 5
Austria: 4
Spain: 4
Hungary: 3
Iceland: 3
Greece: 1
Turkey: 1
Russia: 1
Croatia: 1
Portugal: 1
Convergence of Life Sciences

The Networked Pharma in 2015?

R&D network 2015

- Discovery partnerships
- Licensing agreements
- Equity investments
- Joint Ventures
- Technology deals
- R&D Spin offs

R&D 2005

Sales and marketing 2005 & 2015

21
Regulation and Risk

Life Science – the most heavily regulated industry

**Drivers of Change**

- Demands for greater transparency
  - Disclosing clinical results
  - Pricing strategies
  - Financial controls

- Questions about Pharma’s value proposition
  - Economic value to society

- Concern over regulatory compliance and integrity
  - Complex regulation & authority scrutiny
  - Security of Supply Chain, Products, IT-systems

**Actions to be taken**

- Continuing to ask the right questions in order to mitigate risks and take advantage of new opportunities

  - Demonstrating and communicating the value that pharma companies add to society and shareholders

- Examining their relationships with third parties – from R&D collaborators to retail pharmacies – in addition to their internal controls and standard operating procedures

- Working collaborative with stakeholders in other sectors worldwide to enhance the security and integrity of the pharma supply chain
Global Supply Chain Management

- Product integrity, brand reputation, and patient safety rely on a series of third parties along the supply chain.

- Upstream, risks and opportunities are associated with R&D collaboration, raw materials transactions.

- Downstream, risks and opportunities include diversion, counterfeiting, public safety, and evolving trade laws and regulations.
Global Supply Chain Management

- From factory to customer: a long road…

wholesaler

Short liner

wholesaler

wholesaler

End user
Ernst & Young Global Supply Chain Survey

- Assisted by the Economist Intelligence Unit
- 225 respondents:
  - North America (33 percent), Europe (35 percent), Asia-Pacific (21 percent) represented
  - Pharmaceutical Manufacturers (33 percent), Wholesaler-distributors (31 percent), Pharmacies (24 percent) surveyed
  - 45 percent generate over $100 million in annual sales
  - 37 percent C-Level executives

Distribution – a major risk carrier
  - diversion
  - counterfeits
Regulation and Risk

Taking Effective Action to mitigate Margin Erosion

- Political Lobbying
- Creating ‘best case’
- Argue for non dominance
- Quotas/Cease Supply (non dominance)
- Pricing Corridors
- Accessing data (IMS, Customs, Wholesalers)
- Supply Chain optimisation
- Organisational alignment
- Product Launch Strategies
- Minimising counterfeits
- Developing Product Pricing Strategies
- Creating Day Trading Capability
- Systems & Information Integration and enhancement
- Process and IT Controls integrity
- Sales Force Compliance

- Redesign incentive plans
- Global & Import data aspects
- Automation of performance measurement and assessment
- Understanding volume flows and associated pricing
- Accessing customer/wholesaler data
- Systems integration and control
- Data warehousing
- Argue for non dominance
- Quotas Lease Supply (non dominance)
- Pricing Corridors
Ernst & Young and Health Sciences

Ernst & Young dedicated Health Science Competence Center

Account/Service Line/Client Support

- Business Assessment/Development
- Link to Service Lines
- HS Solutions Development
- Project Support

Dr. Siegfried Bialojan
Mannheim
Industry Leader

Dr. Manuel Bauer
München
Industry Specialist

Dr. Susanne Wosch
Köln
Industry Specialist

Dr. Julia Schüler,
Mannheim
Senior Industry Specialist

Dr. Ira Betz
Mannheim
Knowledge Manager

Nina Dunzweiler
Mannheim
Team Assistant

Thought Leadership/Marketing

- Industry Analysis & Knowledge
- Knowledge Management
- Industry Reports
- Public Relations
- Marketing / Business Relations

Ernst & Young Health Sciences Competence Center
Tel.: +49 621 4208 13 454 - hscc@de.ey.com - www.de.ey.com
Ernst & Young Health Sciences Thought Leadership

"Our Pharmaceutical Reports take up major issues in Pharma and are the basis for the development of specific solutions for clients."

"Our Biotech Reports generate deep understanding of the industry and knowledge to be exploited in client projects."
# Ernst & Young Risk associated Advisory Services

## Value Proposition
Compliance – Cost – Quality - Performance

### Solution Sets

- **Corporate Assurance and Compliance**
  - Internal Audit
  - Financial Reporting Controls
  - IT Assurance & Controls
  - Program & Project Assurance
  - Enterprise Security Mgmt.
  - Forensic Advisory

- **Corporate Management**
  - Corporate Performance Mgmt.
  - Corporate Risk Mgmt.
  - Corporate Accounting and Reporting
  - Treasury Management

- **Corporate Sourcing**
  - Business Process Outsourcing
  - IT Outsourcing
  - IT Service Management
  - Post Merger Integration

### Core Competencies

- Finance Processes, System & Controls
- IT Management, Processes & Controls
- Program & Project Management

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**Ernst & Young**

*Quality is Everything We Do*
Ernst & Young and Pharma Risk Management

Ernst & Young Risk associated Advisory Services

Value proposition

Compliance – Cost – Quality - Performance

Corporate Assurance and Compliance
- Internal Audit
- Financial Reporting Controls
- IT Assurance & Controls
- Program & Project Assurance
- Corporate Accounting and Reporting
- Forensic Advisory

Corporate Management
- Corporate Performance Mgmt.
- Corporate Risk Mgmt.
- Corporate Accounting
- Treasury Management

Corporate Sourcing
- Business Process Outsourcing
- IT Outsourcing
- IT Service Management
- Post Merger Integration

Core Competencies

Health Sciences Solutions

Finance Processes, System & Controls
- IT Management, Processes & Controls
- Program & Project Management

Risk:
- Advanced Security Centers
- Average Sales Price (ASP) Compliance
- Brand Protection
- Contract Assurance
- Corporate Social Responsibility (CSR)
- Data Privacy
- Enterprise Risk Management
- Global Legislative and Regulatory Risk
- Identity and Access Management
- Intellectual Property and Royalty Recovery Reviews
- Internal Audit Outsourcing – Teaming
- Marketing & Advertising Risk Services
- Marketing Mix Optimization
- Medicaid Drug Rebate Program Contract Services
- MMA Brand Impact Analysis
- Sales and Marketing Compliance Assessment
- Security Information Management
- Supply Chain Risk Mitigation
- Risk and Control Anchor Solution
- Wholesaler Audits
Thank you for your attention!

Contact
Health Sciences Competence Center
HSCC@de.ey.com

Phone  (0621) 4208-13454
Fax     (0621) 4208-42102

Theodor-Heuss-Anlage 2
68165 Mannheim