CSL Behring – Aligning Quality Processes

Quality Systems within the wider business

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Presentation Overview

- CSL Company overview
- Aligning Quality Processes
  - The context of process capability across the enterprise
  - Role of metrics and KPIs in ‘Quality Success’
  - Defining the roadmap and setting priorities
  - Agreement on underlying activities
  - Tracking, controlling, and executing alignment

CSL at a glance

CSL is a global specialty biotherapeutics company that develops and delivers innovative biotherapies that save lives, and help people with life-threatening medical conditions live full lives.

US$ 5.5+ Billion
In annual revenue

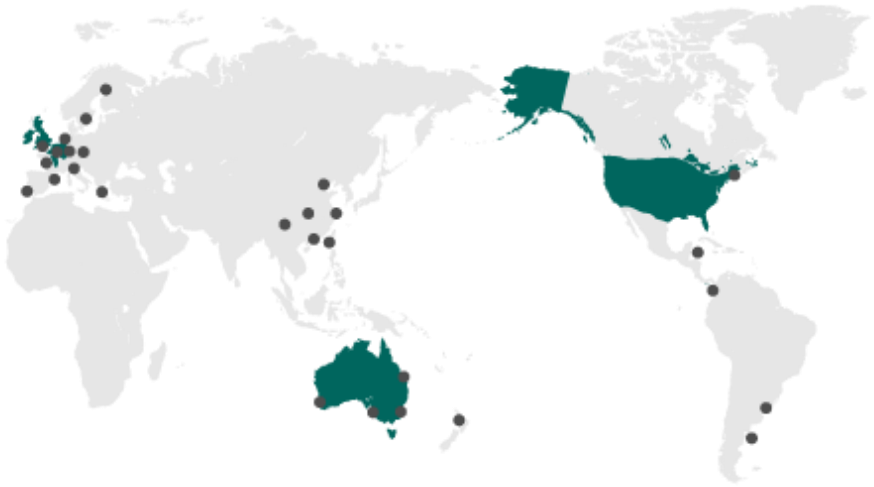
30+ Countries
Operations around the world

16,000+
Employees around the world

1,100+
R&D employees

US$ 2 Billion
In R&D investments in 5 years advances exciting pipeline

130+
Plasma collection centres across Europe and North America



8
manufacturing sites

Australia · Germany · Switzerland · United Kingdom · United States

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Corporate structure

CORPORATE FUNCTION	OPERATIONAL BUSINESSES
CSL R&D	CSL Behring Biotherapies for Life™ Seqirus™ A CSL Company CSL Plasma Good for You. Great for Life.

- Based in King of Prussia, US
- Broadest range of quality products in the industry
- Operations in more than 30 countries, with strong presence in North America, Europe, Asia and Australia

MANUFACTURING OPERATIONS

Bern, Switzerland (1,350 employees)

- Core products: Immunoglobulins
- Specialty products: Albumin, anti-D-hyperimmune, cyto-megalievirus-hyperimmune

Melbourne, Australia (790 employees)

- Plasma fractionation services for Australia, New Zealand, Hong Kong, Malaysia, Singapore and Taiwan
- Core products: Coagulation factors, critical care and immunoglobulins

Marburg, Germany (2,300 employees)

- Core products: Coagulation factors, critical care and immunoglobulins
- Specialty products: IVIg, hyperimmunes

Kankakee, US (1,100 employees)

- Core products: Coagulation factors, alpha$_1$-proteinase inhibitor
- Specialty products: Coagulation factors, albumin

Pre-pasteurization and filling

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Biotherapies for Life™

Coagulation

- Plasma-derived and recombinant factors to treat bleeding disorders

Acquired Bleeding

- Coagulation factor concentrates to prevent or treat bleeding in trauma, childbirth or during operations and bleeding in presence of oral anticoagulants

Immunology

- Immunoglobulins protect against infection for patients with immunodeficiencies and modulate the immune system for patients with autoimmune diseases
- Hyperimmunes are enriched with antibodies directed against a specific target such as preventing hemolytic disease of the newborn

Pulmonary

- $Alpha_1$-proteinase inhibitor to treat patients with $alpha_1$ deficiency and clinical evidence of emphysema

Critical Care

- Products to treat shock, burns, hereditary angioedema, and fluid replacement

Wound healing

- Fibrin sealants used in major surgical procedures

Zemaira®
alpha$_1$-proteinase inhibitor (Human)
Fully focused on Alpha-1

Built on data HUMATE-P®
Antihemophilic Factor/von Willebrand Factor Complex (Human)

BERINERT®
C1 Esterase Inhibitor, Human

Kcentra®
Prothrombin Complex Concentrate (Human)

CSL Plasma
Good for You. Great for Life.

- Based in Boca Raton, US
- One of the world's largest and most sophisticated plasma collection networks
- 130+ collection centres located in the US and Europe
- 5,000+ employees
- Testing laboratories in Knoxville, US and Göettingen, Germany
- Logistics centers in Indianapolis, US and Schwalmstadt, Germany

Boca Raton headquarters


Plasma donor

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- Based in Maidenhead, UK
- Operations in more than 20 countries
- Second largest influenza vaccines provider in the world
- Provides influenza vaccines to both the Northern and Southern hemispheres
- Operates one of the world's largest network of influenza vaccine manufacturing facilities

Seqirus also in-licences and distributes vaccines & pharmaceutical products for Australia & New Zealand.

MANUFACTURING OPERATIONS

Parkville, AUS

- The world's only manufacturer of a vaccine against Q-Fever, and a manufacturer of antivenoms for human use since the 1930s
- Manufactures a range of immunohaematology products (diagnostic reagents)

Holly Springs, US

- Cell culture production, first major advancement in influenza production in over 40 years

Liverpool, UK

- Egg-based production.
- UK's only injectable flu vaccine facility.

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The Business context of process capability

- Quality processes should be viewed within a wider capability of executing a strategy or goal for the business.

- Patient safety always remains *THE* core goal, but the Quality processes capability can be ‘right sized’ for the business complexity and maturity
  - Number of sites
  - Number of products
  - Complexity of operations and throughput

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The Business context of process capability

- Process capability has a relationship with both the management metrics, as well as the support personnel and technology

  (e.g. Number of Overdue deviations > Deviation Process > QA personnel > Deviation System)

- Key elements include:

  Metrics – Measurement and KPIs related to quality processes
  Process – The Quality process with metric output
  People – Specific roles to operate the process
  Technology – Electronic systems to support the process and data

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Role of metrics in ‘Quality Success’

- Metrics for quality should give an indication of the overall ‘health’ of the Quality Systems and create a culture of Quality and Senior management focus on Quality
  - (e.g. Trending of PTCs, or number of repeat deviations)
  - “You can’t manage it if you can’t measure it”
- Quality Metrics are not new in industry but considerations for industry are emerging with recent FDA publications - *Request for Quality Metrics Guidance for Industry – July 2015*
- TGA emphasis on Quality review meetings and Annual Product Review Data
- It is now becoming increasingly important to align Quality Metrics and processes where multiple sites and duplicated manufacturing capabilities exist within a company

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Defining the roadmap and setting priorities

- Consider creating a Quality Systems ‘Roadmap’ to clarify and provide detail on the following:
  - To formulate a clear and concise strategy for Quality Processes and e-systems
  - Demonstrate support of a wider business Strategic Plan to align Quality Processes and supporting e-systems at the *enterprise* level
  - To align and standardise Quality Processes to bring business value
  - To bring industry/regulatory best practice to processes

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Agreement on underlying activities

- Agreement on underlying activities to align quality systems should be based on clear agreed criteria for performance enhancement or prioritisation of investment:
  - Identify where there is business value in best practice, standardise processes
  - Customize only where it brings a competitive advantage or is legally required
  - Drive out inefficient processes
  - Move to industry best practice
  - Automate where it is appropriate to remove cost and improve effectiveness and accuracy

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Tracking, controlling, and executing alignment

- Regular review intervals against strategy and alignment objectives
- Key roles and responsibilities should be defined
- Consider Steering Committee and business sponsors for leadership decisions
- Consider the key role of change management activities
- Clearly define process leads, process owners, and mandates for implementation
- Link project and capital expenditure activity with the ‘roadmap’

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Questions

- Thank you for listening.

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