

QMM Foreign Pilot: Participant Perspective

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Agenda

- **Hovione at a glance**
- **Drivers for Hovione participation**
- **Considerations**

Hovione at a glance

Brief overview of Hovione and Cork site

Hovione is a science-based company providing products and services for the Pharmaceutical Industry

- Founded in 1959
- Privately-held; Stable management; Long term commitment
- Our customers: **Biotechs, medium, speciality and large pharma, and Generics pharma**

Drug
Substance

Particle
Engineering

Drug
Product

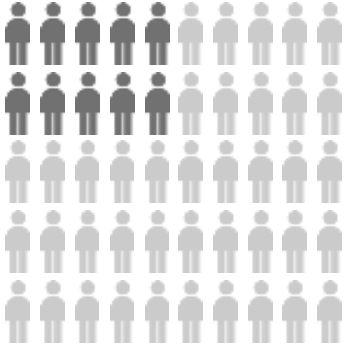


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In it for life

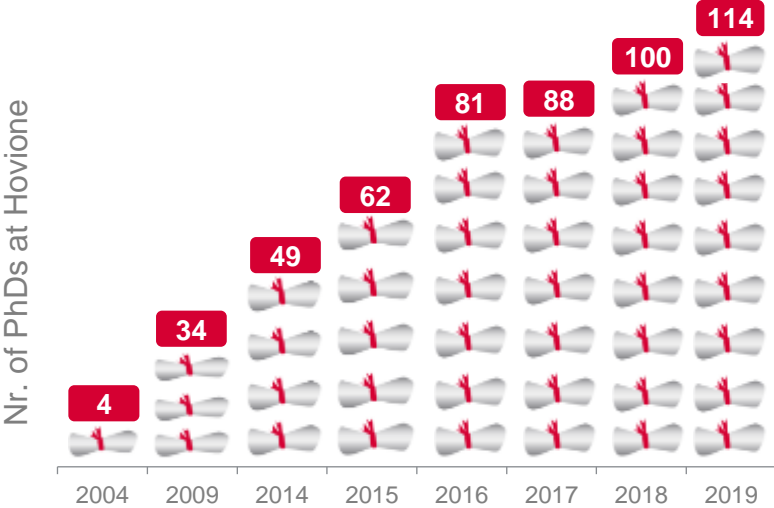
Exceptional People



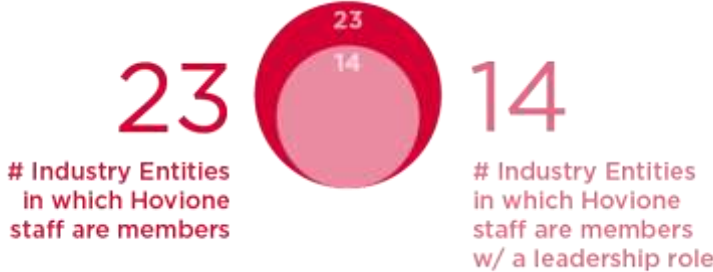
165
R&D Team Members

>7 Years
Average Experience
R&D Team Members

2.000
People all over the world



Professional Membership in Industry Entities



Hovione capacity spread over three continents



- Hovione Sites
- Hovione Offices
- R&D Center



NEW JERSEY, USA
Manufacturing facilities small volume
R&D Labs, Kilo and pilot plant
Sales and marketing for North America



LOURES, PORTUGAL
Manufacturing facilities including
R&D Labs, Kilo and Pilot plants



CORK, IRELAND
Manufacturing facilities



MACAU, CHINA
Manufacturing facilities

Hovione Cork, Ireland

Site Layout



Production Warehouse Office



- Cryogenic - Volume 8000L to 10,000L
- Hydrogenation - Volume 2500L to 6000L
- Large scale spray drying
- Pyrophoric compound handling - 2 stations
- Handling of chlorinated solvents
- Highly Active Substance Material handling Capability



-150° to 120°C



6 to 12 bar



PSD5

Areas of Expertise

People



83

Manufacturing Team members

2

Lean 6σ Black Belts

270

Team Members on site



Technical Services (MS&T) TMs, Average Experience

Site Focus

- Extensive drug substance manufacturing capacity (15 discrete process trains)
- Large scale spray dryer
- Large volume products

Inspections



Quality Control labs / Production Maintenance

Operations



Drivers for Hovione participation

Where opportunity meets a long-standing commitment



Quality Culture and Management Maturity

Hovione's commitment to advance Quality Culture goes back and driven by Senior Leadership



Hovione has a Quality Culture self-assessment program based on 5 key dimensions.



Proactive approach to Quality

- Early adopter of **Process Analytical Technologies** (since 2005)
- Involved in **QbD** submissions as early as 2007
- **Continuous Manufacturing**

Drivers for Participation

- Right tone for companies → focus on Continuous Improvement
- Expectations for Quality Culture → Quality System consistency
- Who's ahead → recognition of Excellence
- Commensurate Regulatory oversight

Considerations...

Our thoughts regarding the participation on the Pilot Program

...on the Assessment

...on the Utility

...on a potential Future Program

...on the Assessment

- Comprehensive
- Topics are all relevant
- Questions sent in advance promotes productive assessment
- Requested evidences easy to produce
- Soft skills of Facilitator is key
- Assessment was fair and report adequate to drive actions
- Improvements suggestions:
 - Questions clustered by topic/SME for fluidity and time
 - Topics weighted for relative impact on QMM

...on the Utility

- Drive continuous improvement
- Internal awareness on QMM via 3rd party assessment
- Influence internal Quality Culture initiative
- Demonstration of QMM to Customers
- Benchmark opportunity

...on a potential Future Program

- Utilization of both F2F assessment and survey/self-assessment
 - **F2F assessment** for periodic review
 - **Survey/self-assessment** for the interim
- **In person** F2F assessment
 - More fluid discussion
 - Allows gathering more evidences
- **Frequency** of assessments to be risk-based
- **Metrics:**
 - To support assessment
 - As interim monitoring
 - Defined with Company for relevance and applicability
- **Dean's list**
- Extend to other firms in the **supply chain**

Any Questions?



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