

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

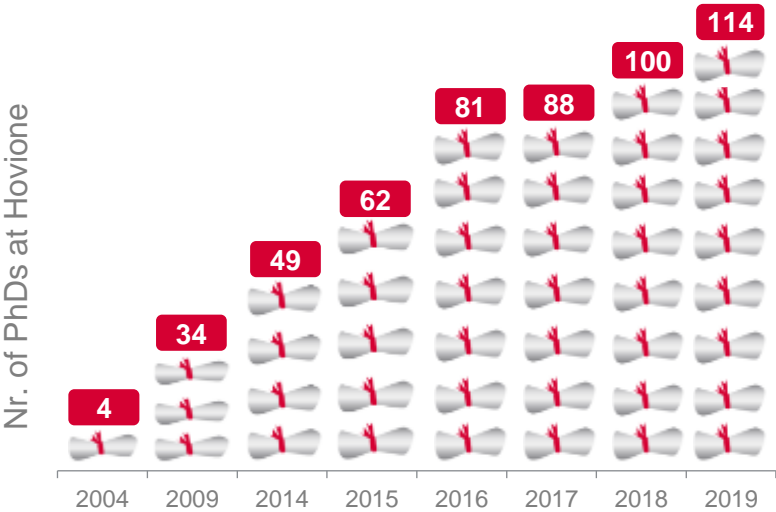
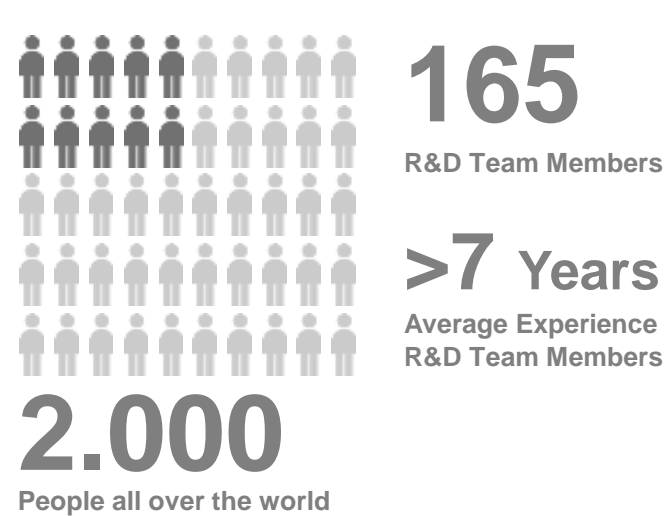


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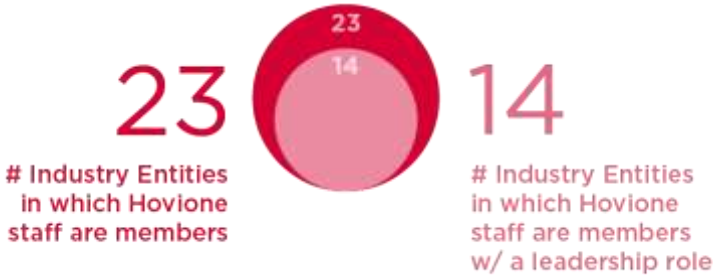


In it for life

Exceptional People



Professional Membership in Industry Entities



Hovione capacity spread over three continents



Hovione Cork, Ireland

Site Layout



Production



Warehouse



Office

People



270

Team Members on site

83

Manufacturing
Team members

2

Lean 6σ
Black Belts



Technical Services (MS&T)
TMs, Average Experience

Areas of Expertise



340 m³

- 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

Site Focus

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

Inspections

24x7

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.



Employee
Ownership

Continuous
Improvement

Technical
Excellence

Leadership
Commitment

Communication
& Collaboration

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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www.hovione.com