



ALMAC

**Journey to Product
Launch Success
Workshop**

San Francisco

16 April 2024



Today's speakers

Guest speaker



Brian Lavery MPharm
Regulatory Affairs Lead



Dawn Douglas
Associate Director –
QP Services



Tommy Burns
Director - Project
Services



Emma Jordan
Associate Director -
Project Services,
Packaging



Brian McNaughton
Director - Commercial
Services



Martin Murphy
Associate Director
Operations, External
Partner Management

Workshop programme



Item	Speaker	Time
Regulatory framework & pathway for supply	Brian Lavery	10:20 – 10:50
EU requirements for Qualified Person (QP) & Responsible Person (RP)	Dawn Douglas	10:50 - 11:20
Transitioning from development to commercial drug product readiness (paediatric case study)	Tommy Burns	11:20 - 11:45
Break		11:45 – 12:00
New Product Introduction (NPI) technical readiness	Emma Jordan	12:00 – 12:25
Product launch & commercial supply strategy – selecting the right model for your unique product	Brian McNaughton	12:25 – 12:50
BioMarin case study – key learnings	Martin Murphy	12:50 – 13:20
Lunch & break into round table discussions		
<ol style="list-style-type: none"> 1. Regulatory & Quality 2. Product development 3. NPI & supply chain 	All	13:20 – 14:10
Networking	All	14:10 -



Almac Group

Introduction

16 April 2024



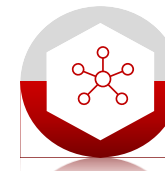
Almac Group overview



Established, global CDMO



Privately owned & financially stable



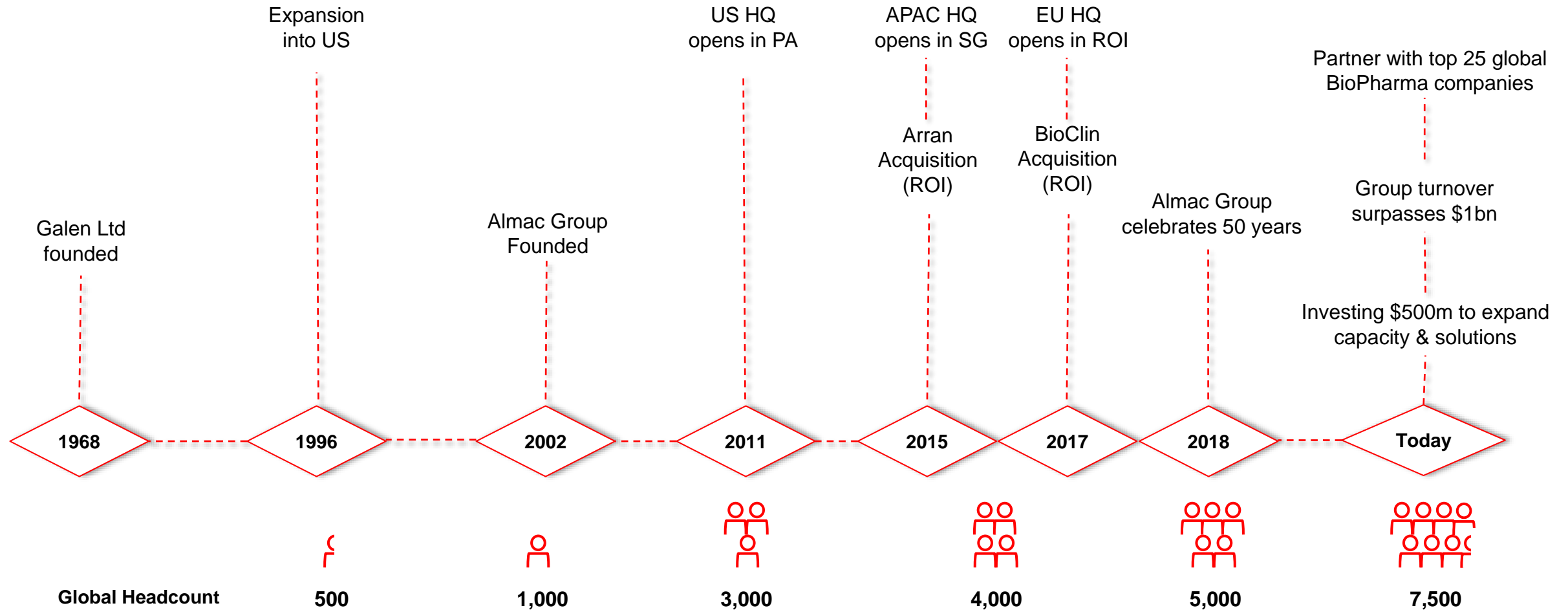
Extensive range of end-to-end solutions



Integrated services from a single source

Our mission is to be your *partner of choice*, providing an expanding array of innovative solutions worldwide

Almac Group growth & stability





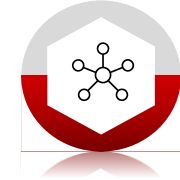
- Pre-formulation
- Non-GMP & early-stage development
- Scale-up & late-stage development
- Clinical manufacture
- High potent manufacture
- Paediatric expertise
- Analytical support



World class project management



Global technical expertise



Global quality management system



- Commercial manufacture
- Commercial packaging
- Specialised / complex assembly
- Product launch (including rapid launch)
- ULT packaging & distribution
- Serialisation solutions
- Commercial storage & distribution
- Specialist support solutions



World class project management



Global technical expertise



Global quality management system



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Journey to Product Launch Success with Almac

1 Framework

Regulatory framework & pathway for supply



2 Support

EU requirements for Qualified Person (QP) & Responsible Person (RP)



Readiness

New Product Introduction (NPI) – process design & development



3 Development to commercial

Transitioning from development to commercial drug product readiness (paediatric case study)

5 Launch & beyond

Understand varying launch and lifecycle models enabling you to select the perfect strategy for your product

