

50+ years expertise

Global regulatory access

World-class capabilities

YOUR TRUSTED PARTNER FOR STERILE INJECTABLE MANUFACTURING

GENERALIST CMO | STERILE SPECIALIST | GROWTH PARTNER



Healthcare. We Care.

EDITORIAL

“

Access to medicine increasingly depends on trusted manufacturing partners capable of delivering the highest standards of quality and regulatory compliance. In this demanding environment, Contract Manufacturing Organizations play a vital role in transforming scientific innovation into safe, reliable therapies for patients around the world. Our mission is to support pharmaceutical and biotechnology companies with the expertise and infrastructure required to bring complex sterile products to market with confidence and to ensure existing products remain available for use.

With advanced facilities, a robust quality system, and experienced teams, we provide comprehensive sterile manufacturing services designed to meet the evolving needs of our partners. From development through commercial production, our capabilities are built on operational excellence, regulatory rigor, and a deep understanding of and respect for sterile manufacture. Every stage of our work is guided by a commitment to precision, reliability, and continuous improvement.

Above all, we believe successful manufacturing is built on strong partnerships. By working closely with our clients, we help accelerate development timelines, ensure supply continuity, and support the delivery of life-changing therapies to patients worldwide. Together, we are shaping the future of sterile pharmaceutical manufacturing.

Martin PRETORIUS
Site General Manager



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WHO WE ARE |



**A trusted European leader
in sterile injectable
manufacturing
for over 50 years**

Combining industrial excellence, regulatory expertise, and operational flexibility, Aspen Notre-Dame-de-Bondeville supports pharmaceutical and biotech partners worldwide in delivering complex injectable medicines safely and reliably.

**Your partner for complex
sterile injectable
solutions, at every scale.**

Since 1968, our industrial site has been a recognized leader in sterile injectable manufacturing in Europe. As a subsidiary of Aspen Pharmacare Holdings Limited, since 2014, we serve pharmaceutical, biotechnology, and generic clients, with significant presence in France, Europe, Japan and US.

OUR MISSION

We transform complex formulations into reliable and accessible medicines. Our expertise also encompasses the manufacturing of sterile pre-filled syringes (PFS), Blow-Fill-Seal ampoules (BFS), active pharmaceutical ingredients (API), and auto-injector devices. We are your trusted partner for your most complex challenges.

OUR MAIN COMPETITIVE ADVANTAGES

European Leadership

- 50+ years of sterile injectable expertise
- Clients in 55+ countries supplied

Global Regulatory Access

- Multi-authority approvals (FDA, EMA, ANSM¹, PMDA², TGA³...)
- Global market access secured

Significant capacity with opportunity to expand

- 100 million PFS
- 55 million BFS
- Broad format capability

Operational Flexibility

- From toll manufacturing to full-service
- 350+ million units/year
- We adapt our capabilities to your needs

GLOBAL PRESENCE



Map Legend

📍 HQ = Head Office ● Sales, Marketing, Distribution & Centres ● Manufacturing Sites

¹ ANSM : French national medicines regulatory agency, operating under the Ministry of Health in coordination with the EMA.

² PMDA : Japan's regulatory authority for pharmaceuticals and medical devices, responsible for marketing approvals and post-market safety monitoring.

³ TGA : Australia's regulatory authority responsible for ensuring the quality, safety and efficacy of therapeutic goods.authorization in Australia.

OUR PARTNERSHIP



One partner
Three market segments
Scalable solutions

Our solutions are built to address the specific challenges of each segment of the global injectable market, combining industrial scale, technical expertise, and long-term partnership.

Tailored partnerships for every injectable market segment

Our solutions are designed for three segments of a growing global injectable market:

TRADITIONAL PHARMA & BIOTECH

- **The Challenge:** Reliable access to PFS/BFS capabilities at competitive cost with rapid qualification timelines.
- **Our Response:** High technology lines with global access and established expertise.

INNOVATORS (GLP-1, VACCINES)

- **The Challenge:** Partner capable of managing complex molecules, future capacities, and rapid scale-up
- **Our Response:** Expanding infrastructure + expertise in advanced formulations

GENERICS & API SUPPLIERS

- **The Challenge:** Economic scale + EU localization + Supply chain reliability
- **Our Response:** Dedicated capabilities + Legacy API expertise + Sustainable partner

FOCUS ASPEN GROUP

- 190 medicines on the WHO Essential Medicines List are manufactured or have been manufactured by our clients.
- 8 million patients in 55+ countries receive treatments from our facilities annually.



QUALITY ACCREDITATIONS & COMPLIANCE |



A fully compliant manufacturing site with approvals from the world's leading health authorities

Our regulatory footprint enables our partners to access the most demanding pharmaceutical markets with confidence.

Meeting the highest global regulatory standards to secure worldwide market access.

World's toughest regulators. Zero compromises. Maximum market access. A business unit with global access.

REGULATORY APPROVALS

ANSM <i>(France, Europe)</i>	FDA <i>(United States)</i>	ANVISA <i>(Brazil)</i>
PMDA <i>(Japan)</i>	TGA <i>(Australia)</i>	EMA <i>(Europe)</i>

+4 Additional Authorities for expanded global reach

QUALITY CERTIFICATIONS

STANDARD	SCOPE	STATUS
ISO 45001	Occupational Health & Safety	Certified
ISO 14001	Environmental Management	Certified
ISO 50001	Energy Management	Certified
GMP <i>(Good Manufacturing Practices)</i>	Pharmaceutical Manufacturing	Approved
Serialization <i>(TRVST/BfArM/KFDA)</i>	Anti-counterfeiting Track & Trace	Compliant

SUSTAINABILITY LEADERSHIP

- **FTSE4Good Index** Constituent | **Top 30 FTSE/JSE Responsible Investment Index**
- **CDP Climate Change: B** Management Level & **CDP Water Security: B-** Management Level
- Complete GHG reporting : Including **Scope 3** Emissions
- Awarded the **EcoVadis Gold Medal**

OUR TECHNICAL CAPABILITIES

Aspen NDB has five core areas of expertise, covering the entire sterile injectable value chain.



PRE-FILLED SYRINGES (PFS)

Total Isolator Filling Technology:

- Up to 350 Million 1ml syringes per year across 3 lines: ETNA, STROMBOLI, VESUVE

Advanced Capabilities

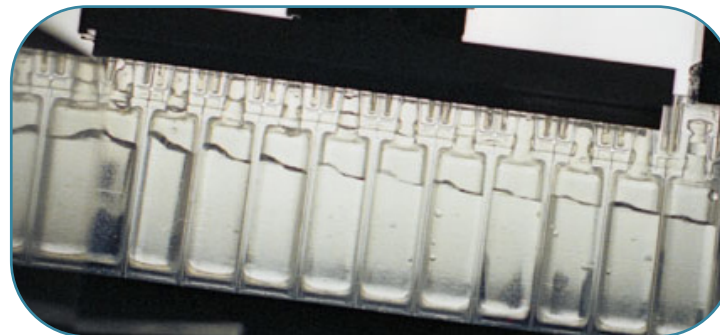
- Aseptic filling or terminal sterilization
- Closed isolator systems for APIs
- Automated visual inspection (detects defects < 50 microns)
- Multiple formats: 8.15 mm, 9.40 mm, 10.85 mm
- Simple to complex molecules including biologics
- Material options: stainless steel, glass, hybrid, single use
- Storage range: ambient to -70°C (2-8°C/-20/-40°C/-70°C)



BLOW-FILL-SEAL AMPOULES (BFS)

Annual Capacity: 55 Million Ampoules

- **PE (Polyethylene):** 40M units/year
- **PP (Polypropylene):** 15M units/year
- Aseptic and terminal sterilization
- Automated visual inspection systems and leak detection for 100% of ampoules



ACTIVE PHARMACEUTICAL INGREDIENTS

Biologic & Chemical Expertise

- **Nadroparin:** 200 batches/year (heparin-derivative, biochemical)
- **Certoparin:** 45 batches/year (heparin-derivative, biochemical)
- **Fondaparinux:** 34 batches/year (chromatographic purification, chemical)
- Scale-up optimisation capabilities
- Quality by Design integration

AUTO-INJECTOR DEVICES

Assembly & Packaging Operations

- **Current (2025):** Semi automated auto-injector assembly capability
- **2027 Target:** Fully automated commercial-ready lines
- Integration of more than 1 device type to allow commercial flexibility
- Infrastructure expansion in progress to support capacity expansion

COLD CHAIN EXCELLENCE

Comprehensive Storage Solutions with global standards

- 7,000 pallet positions (15-25°C)
- 1,300 pallet positions (2-8°C)
- 900 pallet positions (-20/-40°C, 50% interchangeable between temp ranges)
- Ultra-cold storage at -70°C (expanding capacity)
- Electronic TIR/TOR management for traceability
- External logistics partnerships available (storage and transportation)

FULL-SERVICE SUPPORT |



Manufacturing is just the beginning. Partnership is what makes the difference.

We support our partners at every stage of the product lifecycle, combining technical expertise, regulatory guidance, and operational execution.

**One partner.
One team.
One seamless journey to market.**

Manufacturing is just the beginning. We partner with you throughout your entire product journey.

QUALITY CONTROL & ANALYTICS

- Analytical method development & transfer
- Stability testing & PPQ qualification
- Physicochemical & microbiological analysis
- Cleaning validation, Process analytical monitoring & control, Analytical method transfer

MANUFACTURING & TECH TRANSFER

- Lab-to-commercial scale-up
- Technical transfer to production lines
- Formulation & process optimization
- Dose delivery studies (auto-injectors)
- Quality by Design support

VISUAL INSPECTION & PACKAGING

- Automated inspection recipe development
- Probability of Detection (POD) studies
- Packaging technology transfer
- Format/presentation management, flexibility
- Regulatory affairs
- Audit preparation & support (FDA, EMA, etc.)
- Single point of contact: kick-off to commercial launch
- Flexible models: toll manufacturing or full-service partnership
- Qualified Person Release capability

1

Robust data to support quality and regulatory compliance.

2

Seamless transition from development to industrial scale.

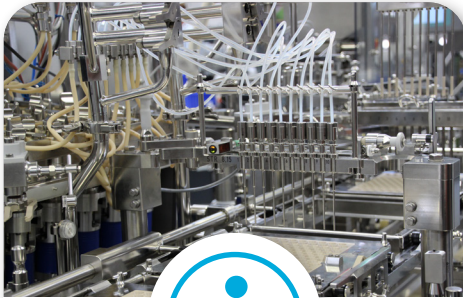
3

Controlled inspection and flexible packaging solutions.

4

One interface. Full regulatory confidence.

OPERATIONAL EXCELLENCE & QUALITY GOVERNANCE |



Operational excellence built on robust quality governance

Our quality governance framework ensures consistent, compliant, and reliable manufacturing at every stage of the product lifecycle.

**Consistency today.
Confidence tomorrow.**

Reliability isn't a promise. It's in our DNA, engineered into every process, every line, every batch, every person.

1/ QUALITY ASSURANCE (QA)

- Full GMP compliance with regular FDA & EMA inspections
- Risk-based approach with FMEA methodology
- Rigorous deviation management & CAPA systems
- Strong internal audit processus
- Strong QA supplier department
- Dedicated QA customer service
- Annex 01 update integration and readiness

2/ QUALITY CONTROL (QC)

- Full physicochemical & microbiological testing
- Raw material & component qualification
- Regulatory-compliant finished product release
- Long-term stability & shelf-life validation

3/ STERILITY ASSURANCE

- 50 years of proven aseptic expertise
- State-of-the-art HVAC systems
- Continuous environmental monitoring (particulates, microbial)
- Validated terminal sterilization processes
- Contamination Control Strategy (CCS) at the core of our business

4/ CONTINUOUS IMPROVEMENT

- **Lean & Six Sigma:** Flow optimization & waste elimination
- **Kaizen Philosophy:** Embedded continuous improvement culture and build capabilities by involving people
- **Project Excellence:** On-time, on-budget delivery
- **Performance Metrics:** On-time delivery, first-pass yield, efficiency KPIs

**“ Compliance is not a constraint.
It is a strategic advantage. ”**

OUR JOURNEY & FUTURE VISION |

EVOLUTION TIMELINE



€160M+ INVESTED & COUNTING

We're not maintaining. We're accelerating. Major investments driving:

- **-70°C ultra-cold storage** for advanced biologics
- **Auto-injector capabilities** (commercial readiness 2027)
- **Next-gen capacity** for GLP-1, breakthrough vaccines, complex molecules, biologics

WHY CHOOSE ASPEN NOTRE-DAME-DE-BONDEVILLE



**More than a CMO.
A long-term partner
for complex injectables.**

In a crowded CMO landscape, Aspen Notre-Dame-de-Bondeville stands out through stability, regulatory reach, and deep injectable expertise.

**Choose confidence.
Choose experience.
Choose performance.
Choose Aspen NDB.**

The CMO market has many players. Here's what sets us apart.



YOUR LONG-TERM GROWTH PARTNER

Stability You Can Count On

- 50 years of uninterrupted operations
- Backed by Aspen Pharmacare (JSE-listed, global pharmaceutical group)
- Financial strength and scale for long-term commitment
- Your projects are strategic partnerships, not transactional contracts
- Proven and reliable sterile capacity



REGULATORY ACCESS, NO BARRIERS

European Leadership Meets Global Reach

- ANSM¹ lead authority across Europe
- FDA, ANVISA, PMDA², TGA³, EMA approved
- Seamless access to world's largest markets
- Consistently successful regulatory inspections



INJECTABLE COMPLEXITY IS OUR SPECIALTY

50+ Years Solving the Toughest Challenges

- Deep expertise across sterile injectable technologies
- Complex formulation capabilities proven at scale
- Biological and biosimilar experience
- Rapid technical transfer capability and capacity

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LEADERSHIP TEAM



Stephen SAAD
Group Chief Executive



Lorraine HILL
Group Chief Operations Officer



Martin PRETORIUS
Site General Manager
Years' experience
Industry : 17 / Aspen : 11
Expertise : Operations leadership, industrial performance, site-wide strategic execution



Olivier GAUTERON
PFS Production & Quality Control
Years' experience
Industry : 27 / Aspen : 12

Expertise : Sterile pre-filled syringe production, PFS line performance & optimization



Sylvain SANNIER
BFS Production
Years' experience
Industry : 25 / Aspen : 11

Expertise : BFS technology operations, quality management, production flow optimization



Olivier HOUSSIN
Engineering & HSE
Years' experience
Industry : 31 / Aspen : 1

Expertise : Engineering projects, maintenance, health, safety & environmental management



Arnaud BEAUDOUIN
Supply Chain & Procurement
Years' experience
Industry : 22 / Aspen : 12

Expertise : Procurement strategy, logistics, inventory optimization, supply chain excellence



Florian BRUTEL
Compliance & Operational Quality
Years' experience
Industry : 20 / Aspen : 8

Expertise : Quality Control, Quality Assurance, Product Quality & Inspection readiness



Alexandre ANDASSE
Projets & Industrialisation
Years' experience
Industry : 30 / Aspen : 12

Expertise : Technical Transfert & Operational Project Management, Global manufacturing operations



Barbara SANCTOT
Transformation
Years' experience
Industry : 28 / Aspen : 12

Expertise : Transformation & Change Management, Performance & Continuous Improvement



Thomas LAGAILLARDE
Finance
Years' experience
Industry : 18 / Aspen : 1

Expertise : Financial management, cost control, performance reporting



Claire NOËL
Human Ressources
Years' experience
Industry : 14 / Aspen : 3

Expertise : Talent management, skills development, HR strategy & employee relations



Yves PICARD
Information Technology
Years' experience
Industry : 30 / Aspen : 12

Expertise : IT strategy, systems performance, digital transformation, Cybersecurity

GET IN TOUCH |

Ready to discuss your next project? We're here to help:



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Part of Aspen Pharmacare Holdings Limited
55+ years of sterile manufacturing excellence
Your partner for injectable pharmaceutical innovation