



aspen

N O T R E D A M E
D E B O N D E V I L L E



Healthcare. We Care.



Aspen is a **global supplier** of branded and generic **pharmaceutical products**



Aspen products are provided in more than **150 countries** around the world. Products are divided in **3 therapeutic categories** : Thrombosis, anaesthetics, cytotoxics



18 manufacturing sites of pharmaceutical products on **6 continents** (North and South America – Asia – Africa – Oceania – Europe)



More than **10 000 employees** all around the world

Manufacturing sites in Europe

3

Aspen Oss, The Netherlands

Acquired in 2013

Manufactures chemical and biochemical active pharmaceutical ingredients

Aspen Notre-Dame-de-Bondeville, France

Acquired in 2014

Manufactures finished form pre-filled syringes

Aspen Bad Oldesloe, Germany

Acquired in 2009

Manufactures finished form tablets, creams, liquids and nebulas





FRAXIPARINE™ / FRAXODI™

Low molecular weight heparin indicated for venous thromboembolic events

95 million units shipped



ARIXTRA™

Unique synthetic injectable inhibitor of Factor Xa approved for a range of uses in VTE treatment/prophylaxis and treatment of acute coronary syndromes

28 million units shipped



MONO EMBOLEX™

Low molecular weight heparin indicated for venous thromboembolic events

6 million units shipped



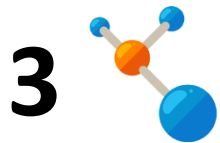
DILUANTS

Production of diluents syringes for third part contractor, used for reconstitution of vaccines prior to injection or oral administration

9 million units shipped

Our key figures

5



3

Active ingredients

692



Employees

92% of production
shipped internationally



(105 countries)

317



SKU shipped

138 Million

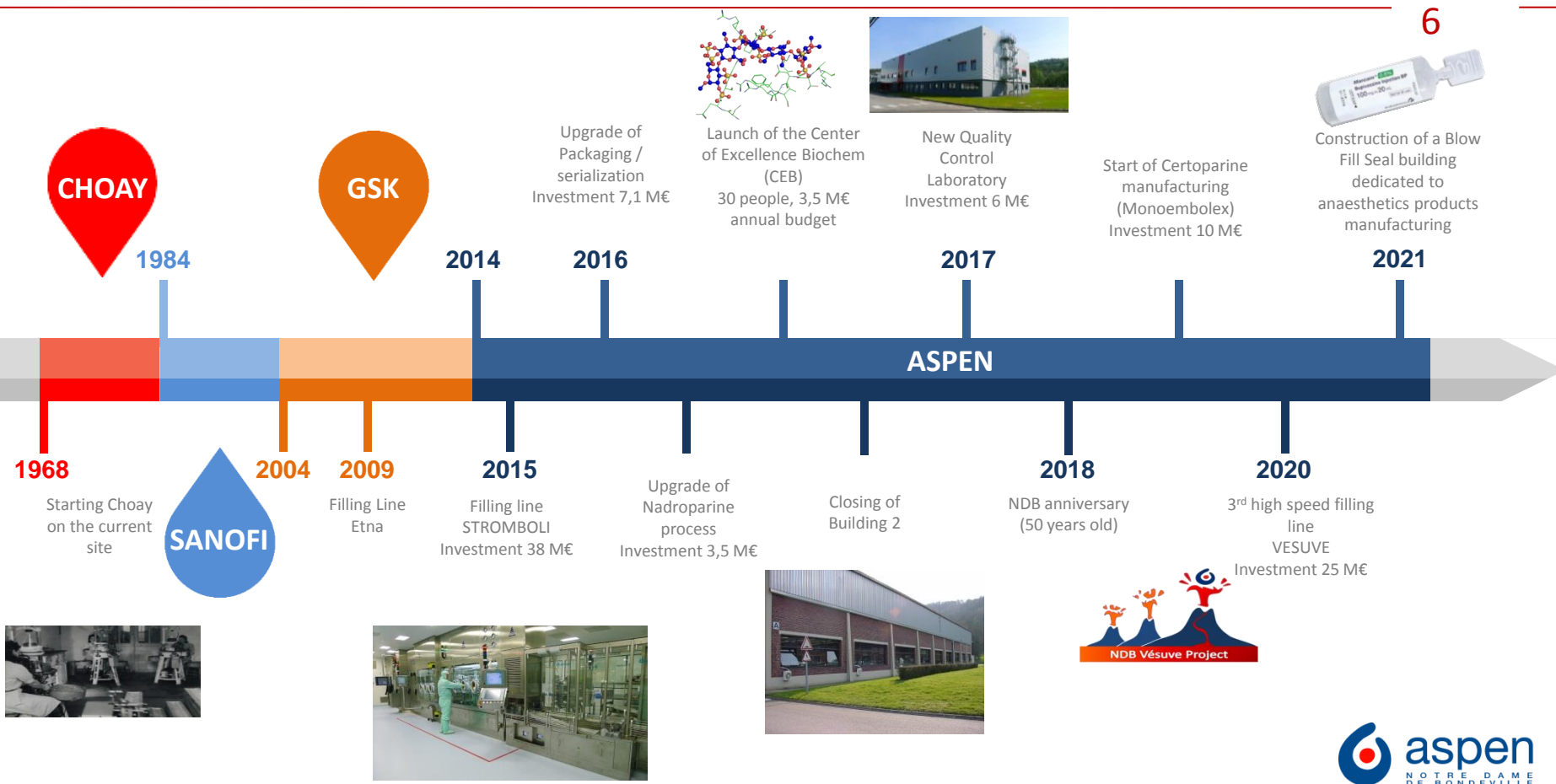
units shipped

90%



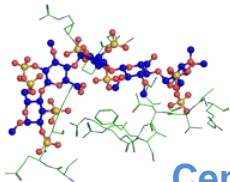
OTIF with an
average of 134 orders per
month

Our history



A site of excellence for the Aspen Group

7



CEB Center of Excellence Biochem

Main mission for the supply chain and production of Biochem ASPEN products :

- Provide **technical support**
- Define a common **quality and regulatory** approach
- Provide supervision from a **performance** and **project management** point of view

The Center of Excellence Biochem will focus on the active ingredients associated with ASPEN's portfolio of anticoagulant products :

Danaparoide sodium (Orgaran®)
Nadroparine calcium (Fraxiparine®/Fraxodi®)
Fondaparinux sodium (Arixtra®)



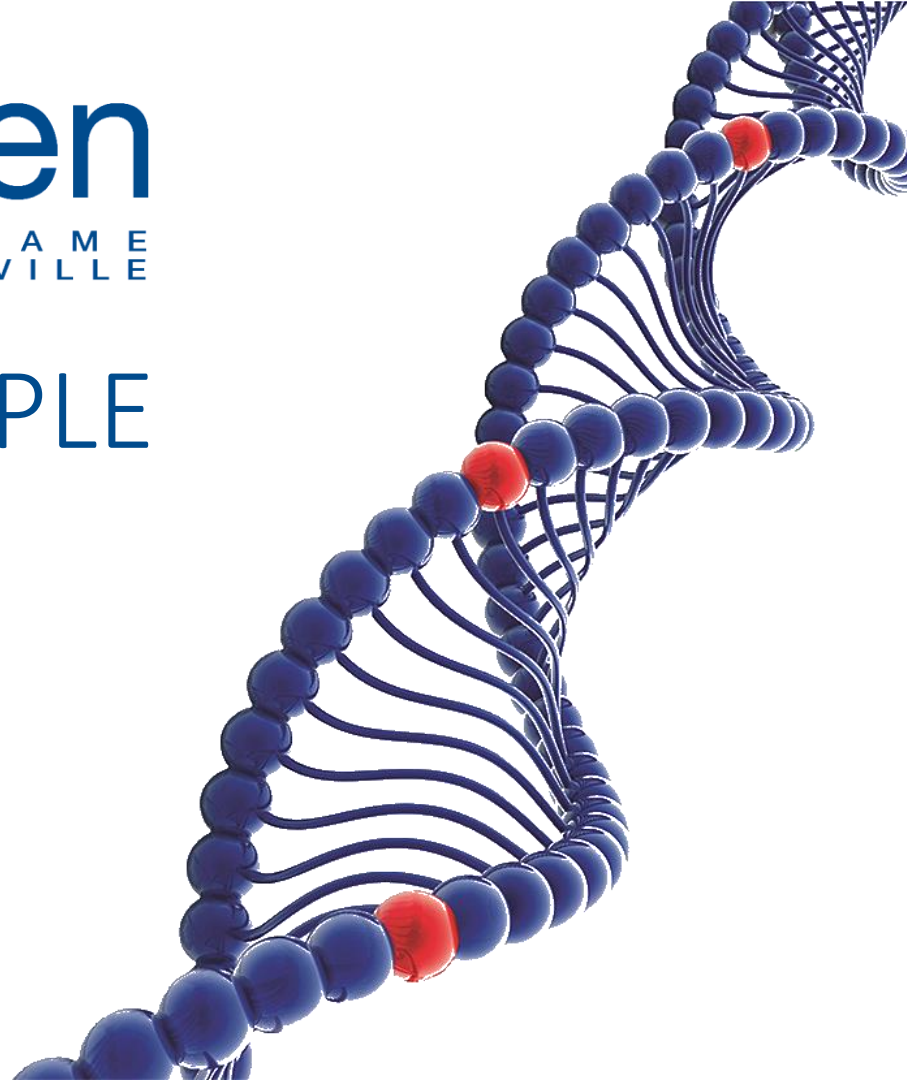
CES Center of Excellence Sterile

- Mutualize **key skills**
- Actively participate in international **conferences, seminars** and **forums** (PDA, SFSTP, PIC, etc.)
- Harmonize **practices** (Quality, Regulation...)
- **Develop skills** / aptitudes for the future
- Assist sites and external partners in **problem solving** and **technology choices**
- Improve the sites and the supply chain **performance**



NDB PEOPLE

Healthcare. We Care.



OUR VALUES

INTEGRITY
INNOVATION
EXCELLENCE
ENGAGEMENT
TEAM WORK



NDB SITE LEADERSHIP TEAM



**QUALITY & RESPONSIBLE
PHARMACIST**
Patrick ROUSSEAU

Director



API & FILLING VS
Ingrid TOUZET

Director



**VISUAL INSPECTION &
PACKAGING**
Simona VLASA

Director



SITE MANAGEMENT
Jean-Charles ROUSSET

Managing Director



LOGISTICS & PROCUREMENT
Arnaud BEAUDOUIN

Director



TECHNICAL
Didier SIMION

Director



S.H.E
Luc PARENT

Director



**TRANSFORMATION, HR &
COMMUNICATION**
Vincent Philibert

Director



FINANCE
Rabah RAFA

Director



LEGAL, ETHICS & COMPLIANCE
Pauline Charles

Senior Manager

792 Employees & Subcontractors



44% women - **56%** men

17 000 h training

Average age **42** years

25 pharmacists

43 on-the-job training students

17 trainees

20 part-time students



Site employees **engaged** to support **local associations**





OUR PRODUCTION EQUIPMENT

Healthcare. We Care.



Our production facilities

14

3 API manufacturing workshops



3 inspection lines



2 sterile filling lines



10 packaging lines



The new quality control laboratory has been launched in 2017:

- Size: 2500 m² sur 3 levels

Quality control laboratory activities: from sample receipt to analysis results

Step 1

Receipt and distribution of samples



Step 3



Results :

- > Analytical review
- > Conformity assessment of components, materials, production environments and products
- > Edition of the certificate of analysis

Step 2

Analysis :

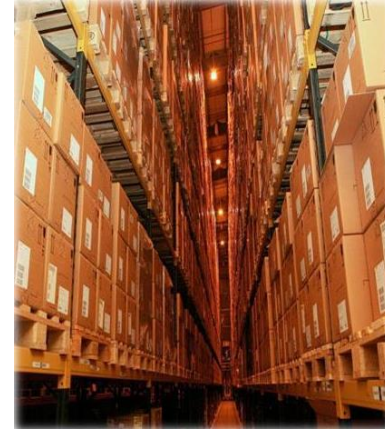
- > Physical Chemistry
- > Microbiology
- > Packaging items control

Warehouse

- Capacity = 7 000 pallets
- Controlled temperature 15-25° C
- Operation 3 shifts x 5 days
- Store and stock status are managed by SAP system

Equipments

- Class C room for sampling operations
- Cold room 2 – 8° C
- Weighing room for raw materials in a close laminar flow hood





OUR COMMITMENTS

Healthcare. We Care.



- [illegible]

- Aspen NDB site has a Management System certified by DQS for OHSAS 18001, ISO 14001 and ISO 50001 standards
- Based on continuous improvement, our SHE policy reflects the management's commitment into areas for progress such as:
 - Reduction of injuries
 - Improvement in Quality of WorkLife
 - Control of energy consumption and quantity of waste
 - Control of environmental aspects and risks of pollution
 - Compliance with our commitments to the authorities and the Aspen Group



Environment performance

20



≈ 2,5 M€

Invested for the environment
since 2010



76 %

reduction from
2010 to 2017



0 waste buried since 2012

Reduction of **33 %** from 2010 to 2017

75 % of waste is recycled



47 %

reduction
from 2010 to
2017