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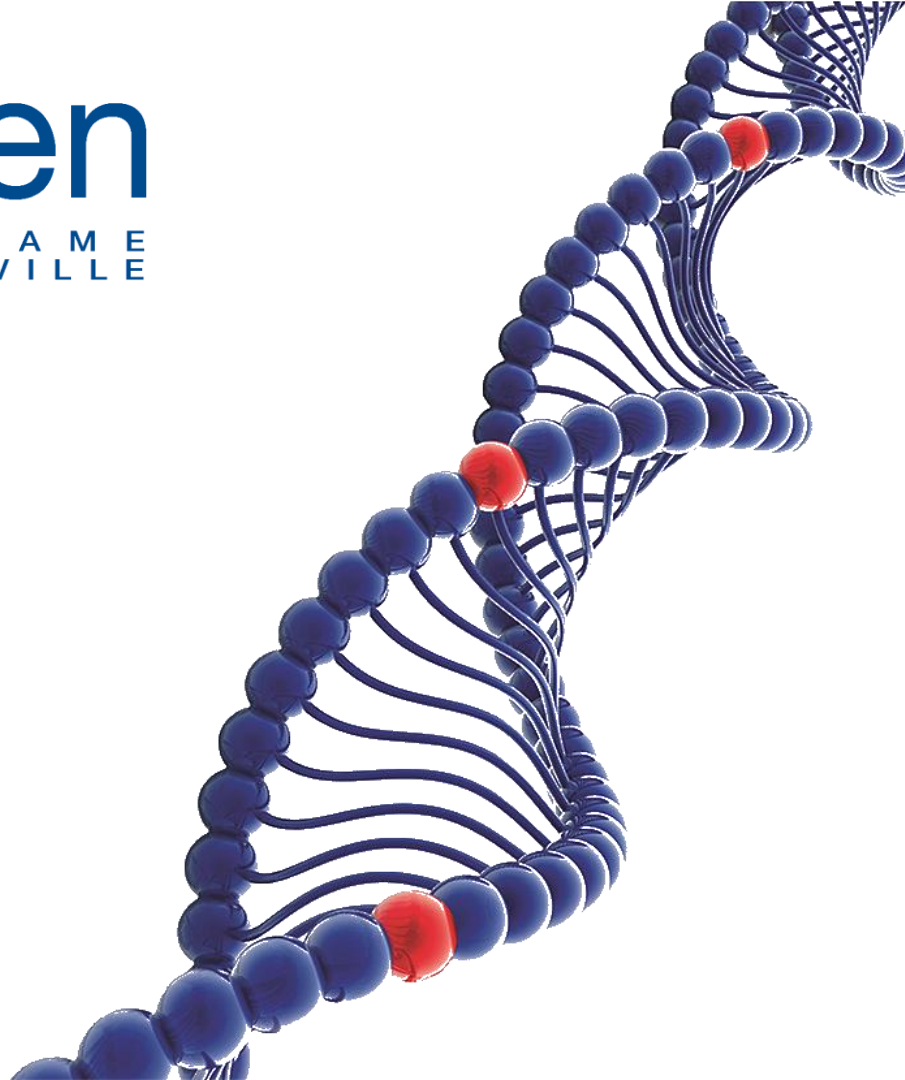

Healthcare. We Care.

Aspen Group

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

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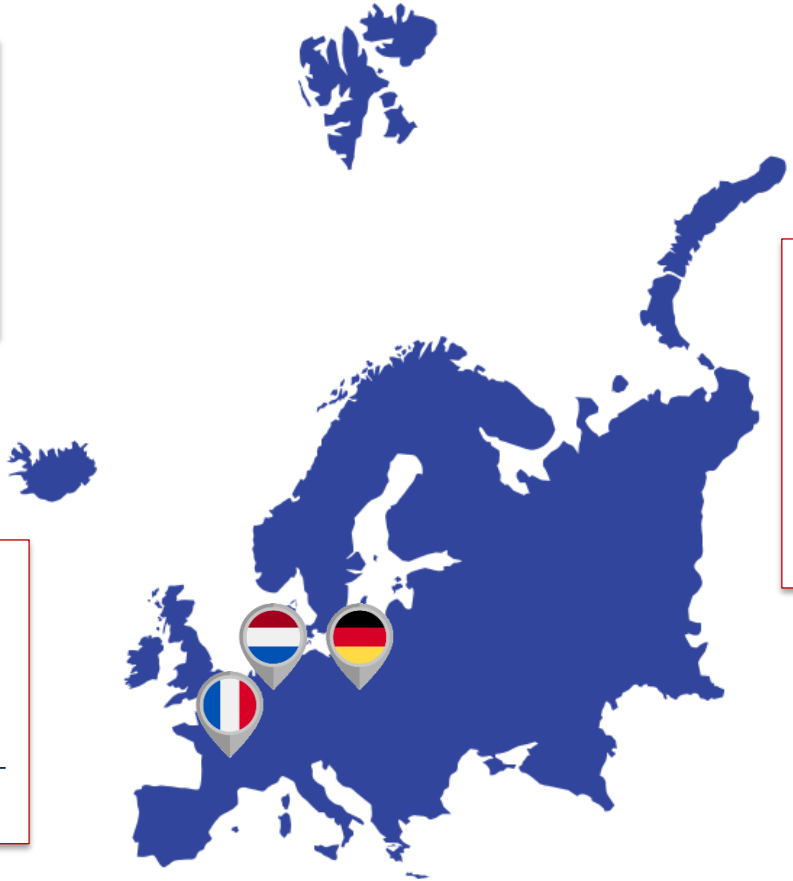
Manufacturing sites in Europe

Aspen Oss, The Netherlands
Acquired in 2013

Manufactures chemical and bio-chemical 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 nebules

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Our Products

FRAXIPARINE ™ / FRAXODI ™

Low molecular weight heparin indicated for venous thromboembolic events

100 millions d'unités

ARIXTRA ™

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

35 millions d'unités

MONO EMBOLEX™

Low molecular weight heparin indicated for venous thromboembolic events

30 millions d'unités

DILUANTS

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

15 millions d'unités

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Our key figures

3

Active ingredients

680

Employees

91% of production shipped internationally

(105 countries)

350

SKU shipped

127 Million units shipped

3285

manufacturing orders

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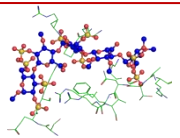
Our history



1968 Starting Choay on the current site

1984 CHOAY

2004 SANOFI

2009 GSK

2014 Filling Line Etna

2015 Filling line STROMBOLI Investment 38 M€

2016 Upgrade of Packaging / serialization Investment 7,1 M€

Upgrade of Nadroparine process Investment 3,5 M€

Launch of the Center of Excellence Biochem (CEB) 30 people, 3,5 M€ annual budget

2017 New Quality Control Laboratory Investment 6 M€

Closing of Building 2

2018 NDB anniversary (50 years old)

Start of Certoparine manufacturing (Monoembolex) Investment 10 M€

2020 3rd high speed filling line VESUVE Investment 25 M€

2021 Construction of a Blow Fill Seal building dedicated to anaesthetics products manufacturing

ASPEN

NDB Vésuve Project

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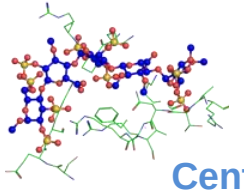
A site of excellence for the Aspen Group



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**

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NDB PEOPLE

Healthcare. We Care.

Our values

OUR VALUES

INTEGRITY
INNOVATION
EXCELLENCE
ENGAGEMENT
TEAM WORK

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NDB SITE LEADERSHIP TEAM

SITE MANAGEMENT
Jean-Charles ROUSSET

Managing Director

QUALITY & RESPONSIBLE PHARMACIST
Patrick ROUSSEAU

Director

LOGISTICS & PROCUREMENT
Arnaud BEAUDOUIN

Director

TRANSFORMATION, HR & COMMUNICATION
Vincent Philibert

Director

API & FILLING VS
Ingrid TOUZET

Director

TECHNICAL
Didier SIMION

Director

FINANCE
Rabah RAFA

Director

VISUAL INSPECTION & PACKAGING
Simona VLASA

Director

S.H.E
Luc PARENT

Director

LEGAL, ETHICS & COMPLIANCE
Pauline Charles

Senior Manager

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NDB PEOPLE (2017)

715 Employees & Subcontractors

48% women - **52%** men

17 000 h training

Average age **42 years**

24 pharmacists

30 on-the-job training students

17 trainees

19 part-time students

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A committed team

Mandela Day

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

LES BLOUSES ROSES
animation loisirs à l'hôpital

APF
Association des Paralysés de France

B2761

LES RESTAURANTS DU CŒUR
LES RELAIS DU CŒUR

métropole
ROUEN NORMANDIE

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OUR PRODUCTION EQUIPMENT

Healthcare. We Care.

Our production facilities

3 API manufacturing workshops

3 inspection lines

10 packaging lines

2 sterile filling lines

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API MANUFACTURING WORKSHOPS

Sodium Fondaparinux: Arixtra™ API

Building U: production launched in September 2004

Purification steps of Fondaparinux

2 shifts 5 days operation

Production capacity: 36 batches of purified Fondaparinux per year

Nadroparin Calcium: Fraxiparine™ API

Launched in 1985

Refurbishment in 2011 – 2012 – 2016

Production capacity: 200 batches per year

1 shift 5 days operation

Sodium Certoparin: MonoEmbolex™ API

Launch of the first validation batches in 2017

Expected volume: 45 batches per year

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SYRINGE FILLING FACILITIES

2 high-speed filling lines:

Etna line : Fraxiparine™ + Arixtra™ + WFI + MonoEmbolex ™

Stromboli line : Fraxiparine™ + MonoEmbolex ™

- Aseptic filling under isolator
- E-beam
- Final sterilization by autoclaving

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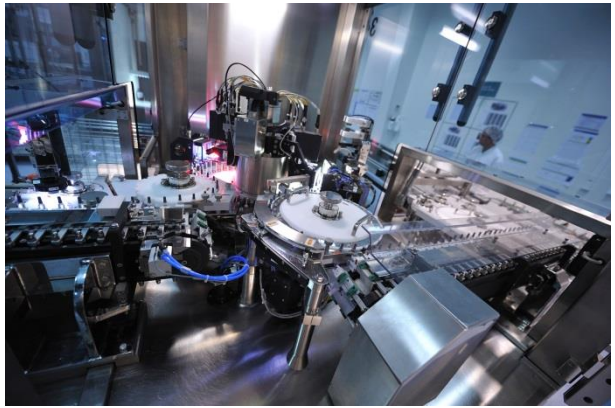
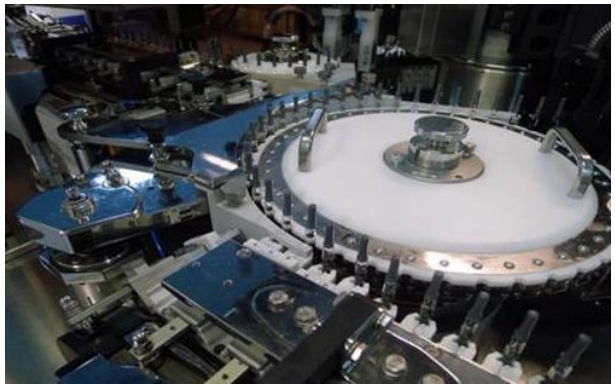
VISUAL INSPECTION



3 inspection lines:

- **Etna line (automatic)**: Fraxiparine™ Arixtra™ Monoembolex™
- **Line 24 Maewa** (automatic): Fraxiparine™, Arixtra™ & diluants
- **Line 20** (semi-automatic): Fraxiparine™ & Arixtra™



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SYRINGE PACKAGING FACILITIES

Fraxiparine™

- **L23 / L15**: Labelling
- **L5 / L4 / L14**: assembling & packaging
- **L 27**: assembling, labelling and packaging

Arixtra™

- **L16**: assembling, labelling & packaging
- **L17**: assembling, labelling & packaging
- **L22**: semi-automatic packaging
- **L25**: packaging line dedicated to Japan

MonoEmbolex™

- L16: assembling, labelling & packaging
- L17: assembling, labelling & packaging

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QUALITY CONTROL LABORATORY

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 2

Analysis :

> Physical Chemistry

> Microbiology

> Packaging items control

Step 3

Results :

> Analytical review

> Conformity assessment of components, materials, production environments and products

> Edition of the certificate of analysis

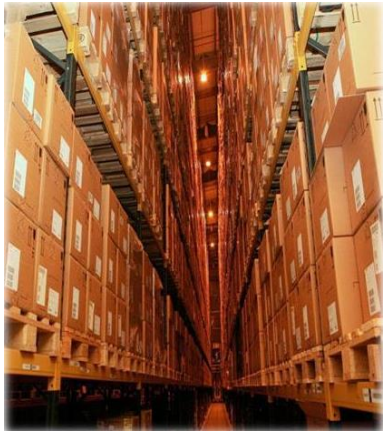
WAREHOUSE

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



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OUR COMMITMENTS

Healthcare. We Care.

Quality commitment

- It’s a team of women and men who supports the manufacturing department. Their target is to put on the market safe, effective and quality medicines
- 24 pharmacists work on site. 8 of them are entitled to batch release
- Quality missions are as follows:
  - Buildings and equipment
  - API and packaging components
  - Manufacturing
  - Packaging
  - Finished product control
  - Continuous improvement

Health, Safety, Environment

- 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


POLITIQUE SANTÉ, SÉCURITÉ ENVIRONNEMENT

Le Site Aspen Notre Dame de Bondeville est spécialisé dans la fabrication de produits stériles ; de la production du principe actif à la fabrication du produit fini pharmaceutique. En tant qu'entreprise de santé, nous sommes attentifs aux attentes sociétales en termes de transparence, d'éthique, d'équité, de respect des Hommes et de l'Environnement dans un contexte réglementaire en constante évolution.

Pour répondre à tous ces enjeux, la Direction du Site alloue les moyens nécessaires pour déployer et faire appliquer cette politique à tous les niveaux hiérarchiques. Chaque collaborateur connaît son rôle et ses responsabilités en matière de Santé, de Sécurité et d'Environnement et participe activement à la prévention des risques et des pollutions, ainsi qu'à l'amélioration de la performance énergétique.

Cette politique s'applique à l'ensemble des collaborateurs ASPEN NDB, aux intervenants extérieurs ainsi qu'aux visiteurs.
Les principes fondamentaux qui caractérisent l'engagement de la Direction sont :

- La conformité à la réglementation en vigueur et aux autres exigences, notamment celles du groupe Aspen
- L'amélioration continue des performances SSE, basées sur la prévention des accidents et des pollutions,
- L'identification des situations à risque par l'ensemble des salariés et leur réduction,
- L'intégration des aspects SSE dans tous les projets, de la conception à la réception,
- Le respect par tous les salariés des règles et exigences SSE.

Ces principes se déclinent dans des axes de progrès tels que :

- La réduction de l'accidentologie,
- L'amélioration de la Qualité de Vie au Travail,
- L'amélioration de notre performance environnementale (énergies, déchets, rejets dans l'air et dans l'eau),
- L'amélioration de notre performance énergétique en favorisant des achats intégrant une approche écoresponsable,
- La maîtrise des aspects environnementaux et des risques de pollution,
- Le respect de nos engagements vis-à-vis des autorités et du groupe Aspen.

Ces axes de progrès, cohérents avec le Programme Annuel de Prévention, seront mis à jour au minimum une fois par an en revue de Direction.

NDB le 28/02/2017

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SSE Santé Sécurité Environnement

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Environment performance

≈ 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

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