



aspen

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

Aspen group

- Aspen is a **global supplier** of branded and generic **pharmaceutical products** as well as infant nutritional and consumer **healthcare products** in select territories.
- Supplier of branded and generic pharmaceuticals in more than **150 countries** around the world.
- The **6th** largest generic company in the world (June 2015)
- **18** manufacturing sites of pharmaceutical products on **6 continents** (North and South America – Asia – Africa – Oceania – Europe)
- One of the **largest pharmaceutical companies** in the southern hemisphere
- **10 000 employees** around the world



Manufacturing sites in Europe



Aspen Bad Oldesloe, Germany

- Acquired in 2009
- Manufactures finished form tablets, creams, liquids and nebules



Aspen Oss, 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

WHO
ARE
WE?

Our products



FRAXIPARINE™/ FRAXODI™

Low molecular weight heparin indicated for venous thromboembolic events
91 million units shipped



ARIXTRA™

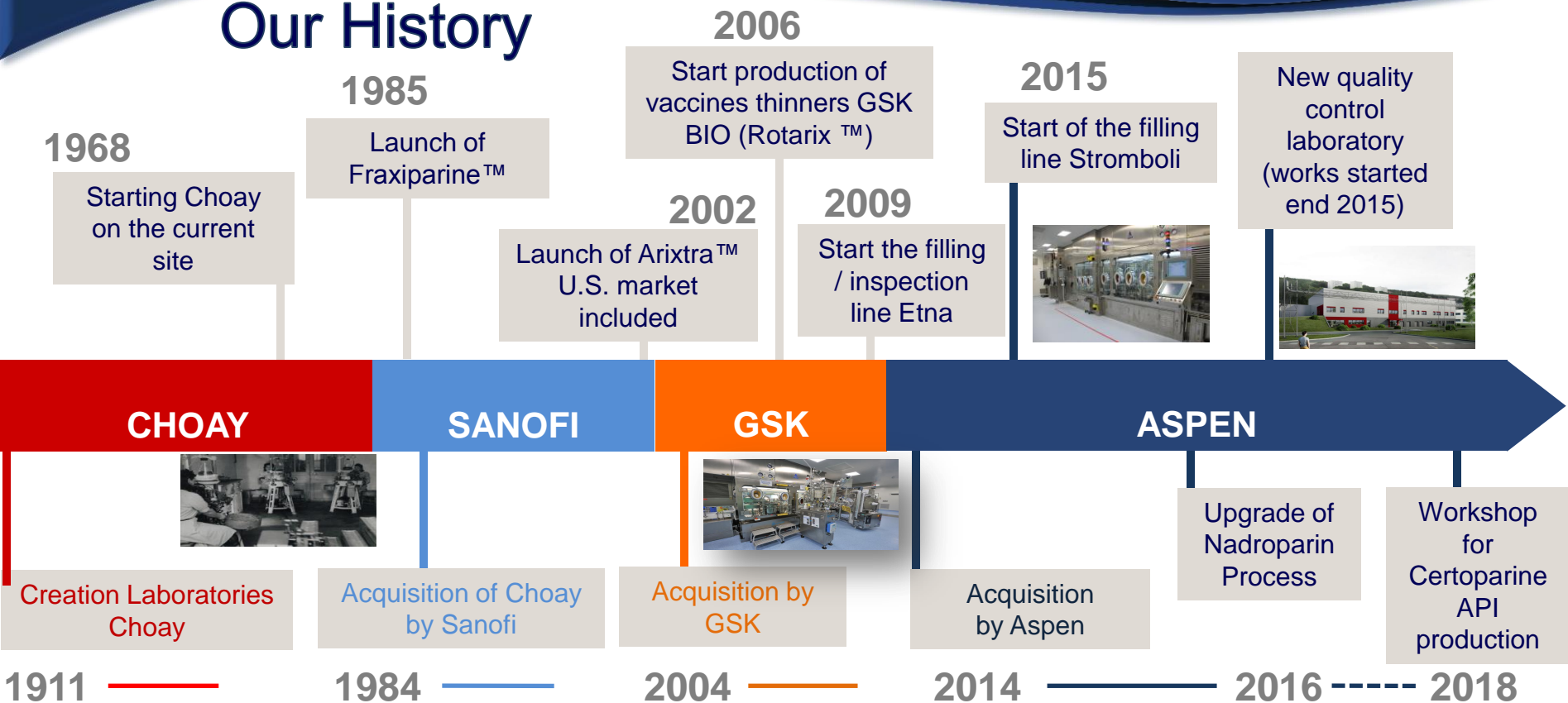
Small molecule inhibitor of Factor Xa indicated for the prevention of deep vein thrombosis
32 million units shipped



DILUENTS

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


Our History



Our key figures

2 
Active ingredients

 **5**
products

123  markets
90% of production
shipped internationally

330 
references shipped
143 Million units
shipped

3391 
manufacturing orders

 **777**
Employees
and subcontractors
(August 16)

Notre-Dame-de-Bondeville Site



Women and men of NDB*

OUR VALUES

INTEGRITY
INNOVATION
EXCELLENCE
ENGAGEMENT
TEAM WORK



Our Site Leadership Team

Operating Officer et Pharmacien
Responsable Groupe Aspen
Lorraine Hill



SITE MANAGEMENT
Jean-Charles ROUSSET
Director



**QUALITY ASSURANCE &
RESPONSIBLE PHARMACIST**
Director
Patrick ROUSSEAU



FINANCE
Rabah RAFA
Director



STERILE PLATFORM PROJECT
Wladimir GUITEL
Director



API and FILLING VS
Ingrid TOUZET
Director



HUMAN RESOURCES
Benoît DE VERGNETTE
Director



TECHNICAL
Virginie LEBIDOIS
Director



**INSPECTION & Fraxiparine
PACKAGING**
Yves POME- BAUDRES
Director



S.H.E
Luc PARENT
Director



LOGISTICS
Arnaud BEAUDOUIN
Director



**STRATEGY &
COMMUNICATION & Arixtra
PACKAGING**
Simona VLASA
Director



TRANSFORMATION
Vincent PHILIBERT
Director



PROCUREMENT
Rémy BOUDSOCQ
Director



**LEGAL, ETHICS &
COMPLIANCE**
Alexandre ROMAND
Senior Manager

Women and Men of NDB (in 2016)



47% women - 53% men



15,167
training hours

Average age **42 years**

23 pharmacists



51 trainees

31 part-time students

A committed team

Site employees engaged to support **local associations**



Our production equipment

Our production facilities

2 API manufacturing workshops



3 inspection lines



2 sterile filling lines



11 packaging lines



Fondaparinux Facility

- **Sodium Fondaparinux: Arixtra™ API**

- ✓ Building U: production opened in September 2004
- ✓ Purification steps of Fondaparinux crude
- ✓ 2 shifts x 5 days operation
- ✓ In 2015 : 19 batches of purified Sodium Fondaparinux



Heparin Facility

- **Nadroparin Calcium : Fraxiparine™ API**

- ✓ Launched in 1985
- ✓ Refurbishment in 2011-2012-2016
- ✓ Volume 2015 : 108 batches
- ✓ 1 shift x 5 days operation



Certoparin Facility

Sodium Certoparine:

Mono embolx™ API

10 millions €uros of investment

- ✓ Ongoing work on process optimisation, product transfert and infrastructure of the new facility
- ✓ **Launch of the first validation batches** planned in **2017**
- ✓ Expected volume: **45 batches** per year



Syringe filling facilities

- **2 filling lines:**
 - ✓ Etna line: Fraxiparine™ + Arixtra™ + WFI
 - ✓ Stromboli line: Fraxiparine™
- Aseptic filling under isolator
- Final sterilisation by autoclaving



Stromboli line

New high speed filling line with the highest quality standards for the production of sterile prefilled syringes

38 millions €uros invested

Start of production : October 2015

Line capacity :

36 000 syringes / hour

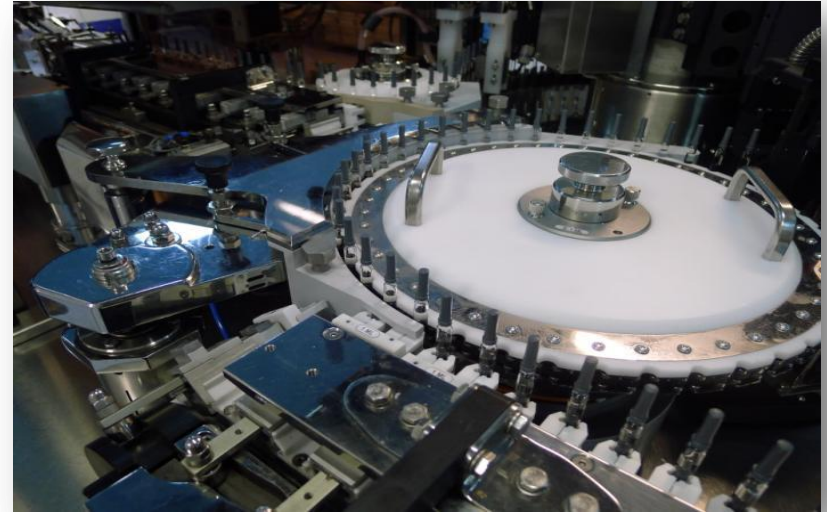
130 millions of syringes maximum per year



Syringe Inspection facilities

- **3 inspection lines :**
 - ✓ Etna automatic: Fraxiparine™ & Arixtra™
 - ✓ L24 Maewa automatic inspection : Fraxiparine™, Arixtra™ & diluents (*).
 - ✓ L20 semi-automatic: Fraxiparine™ & Arixtra™

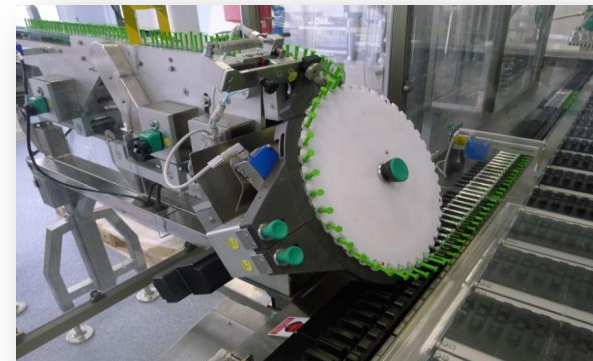
(*) production line for US market



Syringe Packaging Facilities

- **Fraxiparine™**
 - ✓ L15 / L23: labelling lines
 - ✓ L 2 / L4 / L5 / L14: assembling & packaging lines
 - ✓ L 27: labelling, assembling and packaging line
- ✓ **Arixtra™**
 - ✓ L16 : assembling, labelling & packaging line
 - ✓ L17 : assembling, labelling & packaging line*
 - ✓ L22 : semi-auto packaging line
 - ✓ L25 : packaging line dedicated to Japan

* US line



New quality control laboratory

Building of a new quality control laboratory near production workshops

6 millions €uros of investment

Laboratory of 2500 m² on 3 levels



octobre 2015 :
Starting of
construction

Novembre 2016 :
Delivery of building

1^{er} trimestre 2017 :
transfert of analytical
activities

Our commitments

Quality Commitment ...

Quality is at the heart of our business. The Aspen Notre Dame de Bondeville site has received certifications and is regularly audited by the following health authorities:

Brazil



**Agência Nacional
de Vigilância Sanitária**

France



Canada



Japan



Europe



USA



Health, Safety, Environment

Aspen NdB site has a Management System certified by DQS for OHSAS 18001 and ISO 14001 standards.

Based on continuous improvement, our SHE policy reflects the management's commitment into areas for progress such as:

- ✓ Reduction in 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



HEALTH, SAFETY & ENVIRONMENT POLICY

HEALTH, SAFETY & ENVIRONMENT POLICY

The Aspen Notre-Dame-de-Bondeville site is specialized in the manufacture of sterile goods ranging from the production of the active ingredient to the manufacture of the finished pharmaceutical product. As a healthcare company, we are attentive to societal expectations in terms of transparency, ethics, fairness and respect for people and the environment in a regulatory context which is continuously changing.

To meet all these challenges, the site Management allocates the resources needed to deploy and apply this policy at all the company levels. Each member of staff is acquainted with his/her role and responsibilities with respect to the Health, Safety and Environment policy and is active in the prevention of risks and pollution.

This policy applies to all ASPEN NDB employees, contractors and visitors.

The fundamental principles that characterize the Management's commitment are:

- Compliance with the regulations in force and other requirements, notably those of the Aspen group.
- Continuous improvement of the SHE performance levels, based on the prevention of accidents and pollution.
- The risk assessment by all employees and their resolution.
- Compliance with the SHE rules and requirements by all the employees.

These principles are broken down into areas for progress such as:

- Reduction in 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.

These areas for progress, consistent with the Annual Prevention Program, will be updated at least once a year in the Management review.

NDB, 28/09/15



Environment performance

2,3 millions €

invested for the
environment
since 2011



waste

0 waste buried since 2012

Reduction of **20%** in 6 years

80% of waste is recycled



Energy savings

25% reduction in 6 years



Water consumption

40% reduction in 6 years

Complementary instructions during the visit



Foot protective shelves
must be worn inside facilities



Photos
Photos/videos of equipments
and employees are
forbidden within the site
without prior written
permission from direction.



**Respect pedestrian
traffic**

Use the pedestrian walkways
both inside and inside buildings.
It is forbidden to walk outside
the painted lines



Products
It is forbidden to touch the
products during the visit in
facilities

THANK YOU!