



aspen

NOTRE DAME
DE BONDEVILLE

GENERAL PRESENTATION



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



16 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

850 employees

Manufactures chemical and biochemical active pharmaceutical ingredients

Aspen Notre-Dame-de-Bondeville, France

720 employees

Manufactures finished form pre-filled syringes

Aspen Bad Oldesloe, Germany

450 employees

Manufactures finished form tablets, creams, liquids and nebulas





FRAXIPARINE™ / FRAXODI™

Low molecular weight heparin indicated for venous thromboembolic events

100 million units



ARIXTRA™

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

30 million units



MONO EMBOLEX™

Low molecular weight heparin indicated for venous thromboembolic events

30 million units



DILUANTS

Production of diluents syringes for GSK vaccines, used for reconstitution of vaccines prior to injection or oral administration

15 million units



DILUANTS NaCl

Production of diluents syringes for Sanofi Pasteur, used for reconstitution of *Hæmophilus influenzae* type B vaccines for Japanese Market

5 million units




FLU VACCINES


Production of vaccines for Sanofi Pasteur (filling & inspection). First campaign in 2023

10 million units

Our key figures (2019)

3 
Active ingredients

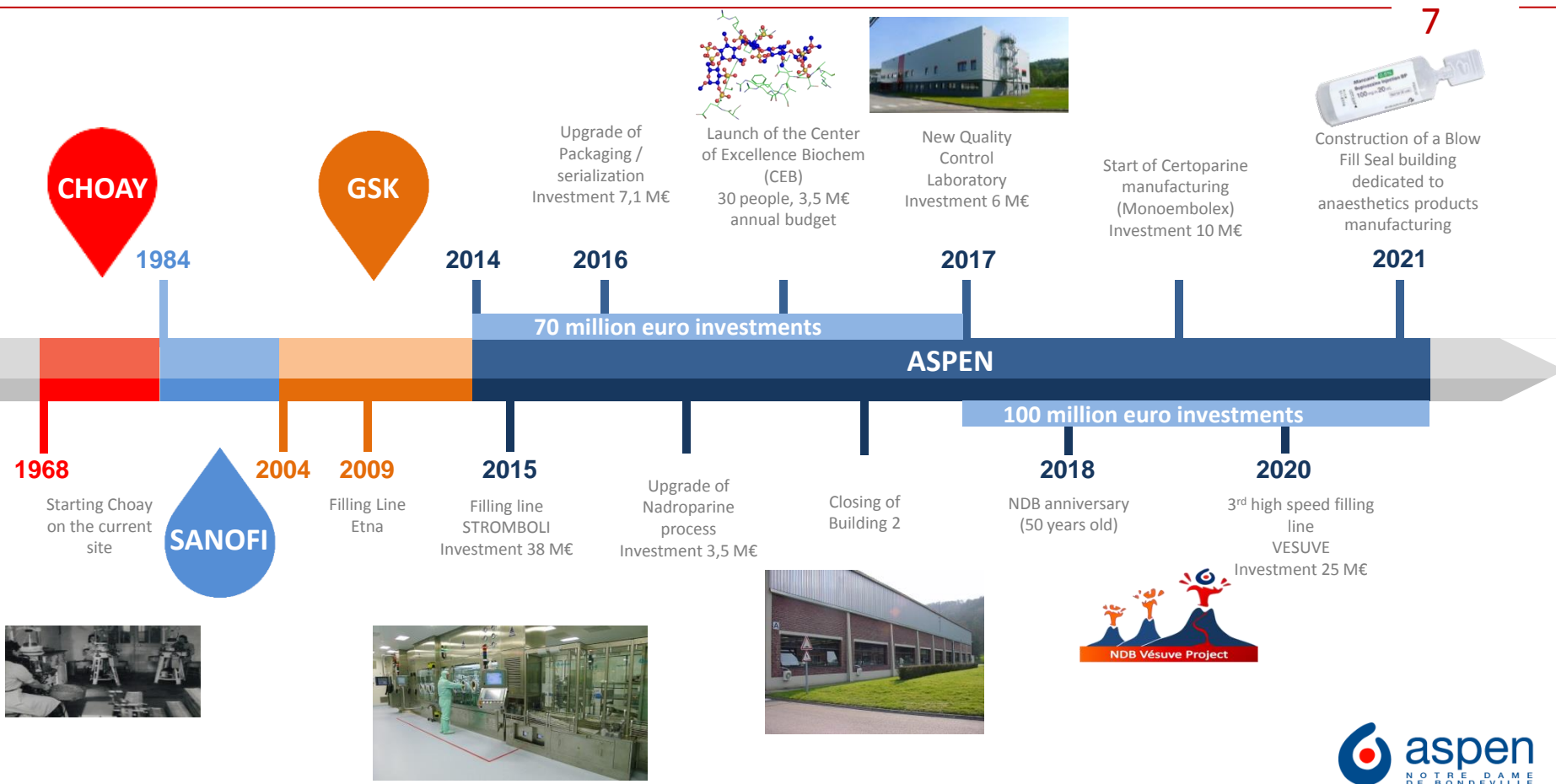
725 
Employees

92% of production
shipped internationally 
(105 countries)

300 
SKU shipped

145 Million 
units shipped

Our history



Since the acquisition of Notre Dame de Bondeville site by Aspen group in May 2014, nearly **70 million euros** have been invested in production facilities to increase production capacity and accommodate new products:

- ➔ New high speed filling line with the highest quality standards for the production of sterile prefilled syringes (36,000 syringes per hour), inaugurated in October 2015: **€ 38 million**
- ➔ A new raw material manufacturing workshop (Certoparine): **€ 9 million**
- ➔ A new quality control laboratory, inaugurated in April 2017: **€ 6.3 million**
- ➔ The modernization of heparin purification workshop to increase the production capacity of raw materials: **€ 3.4 million**
- ➔ Improvement of packaging lines, with the installation of new thermoforming , labeling and cartoning equipments: **€ 7.1 million**

15

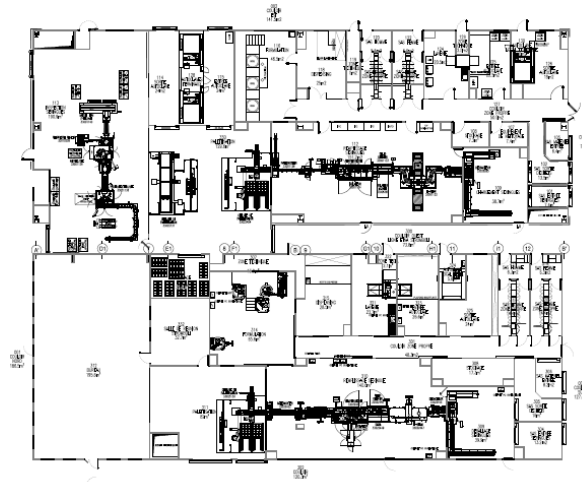
Million euro investments

60 000

Syringes/hour

2020

Operational



380

Million
PFS capacity

ETNA

80 Million units

STROMBOLI

120 Million units

VESUVE

180 Million units

PFS – fourth inspection line

10

5

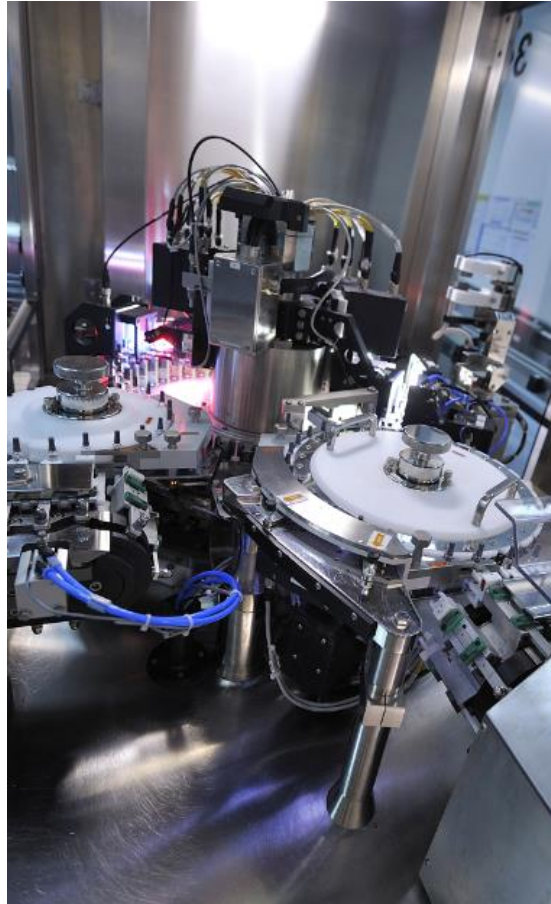
Million euro investments

36 000

Syringes/hour

2020

Operational



22

Cameras

3

Spectrometers

VULCAIN

Vesuve's inspection line

New product portfolio : anesthetics

65

Million euro investments

46

Million single doses ampules
(polyethylene and polypropylene)

2

Million infusion bags



100

recruitments

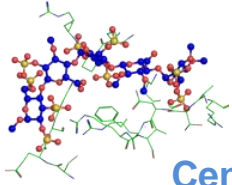
8000

M²



1

new production building



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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NOTRE DAME
DE BONDEVILLE

NDB PEOPLE












Healthcare. We Care.



OUR VALUES

- INTEGRITY
- INNOVATION
- EXCELLENCE
- ENGAGEMENT
- TEAM WORK

NDB SITE LEADERSHIP TEAM

 <p>QUALITY & RESPONSIBLE PHARMACIST Ingrid TOUZET</p> <p>Director</p>	 <p>SITE MANAGEMENT Jean-Charles ROUSSET</p> <p>Managing Director</p>	 <p>FINANCE Rabah RAFA</p> <p>Director</p>
 <p>PRODUCTION Simona VLASA</p> <p>Director</p>	 <p>LOGISTICS & PROCUREMENT Arnaud BEAUDOUIN</p> <p>Director</p>	 <p>TRANSFORMATION, HR & COMMUNICATION Vincent Philibert</p> <p>Director</p>
	 <p>TECHNICAL Didier SIMION</p> <p>Director</p>	 <p>LEGAL, ETHICS & COMPLIANCE Pauline Charles</p> <p>Senior Manager</p>
	 <p>S.H.E Luc PARENT</p> <p>Director</p>	

825 Employees & Subcontractors



44% women - **56%** men

Professional equality score **90/100**

76 on-the-job training students

21 trainees

29 part-time students

42 years Average age

13 228 h training

24 pharmacists

A committed team



Site employees engaged to support local associations



Don de la Société ASPEN

Au sein du site pharmaceutique ASPEN de Notre Dame de Bondeville en Seine-Maritime, des bénévoles s'engagent pour assurer la santé et la sécurité au travail. En plus de cet engagement au sein de l'entreprise, envers leurs collègues, ces hommes et femmes font preuve d'une grande générosité en menant des actions tout au long de l'année au profit des associations.

C'est ainsi que pour la deuxième année consécutive, les pompiers bénévoles d'ASPEN ont pris l'initiative d'organiser la vente de calendriers et décidé de faire profiter l'argent ainsi récolté à trois associations de leurs coeurs, dont Xzaordinaire. 246 € ont ainsi été récoltés pour l'association Xzaordinaire.

La société avait donc décidé d'organiser un lunch sur le site de l'usine le vendredi 05 octobre dernier pour remercier les pompiers aux grands cours et remettre les dons aux 3 associations.

Une nouvelle fois, c'est avec une grande émotion que nous remercions chaleureusement tous ces bénévoles pour leur engagement fidèle envers Xzaordinaire.

Adélaïde Degandès



A dynamic community





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OUR PRODUCTION EQUIPMENT



Healthcare. We Care.

3 API manufacturing workshops



4 inspection lines



5 packaging lines



3 sterile filling lines

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



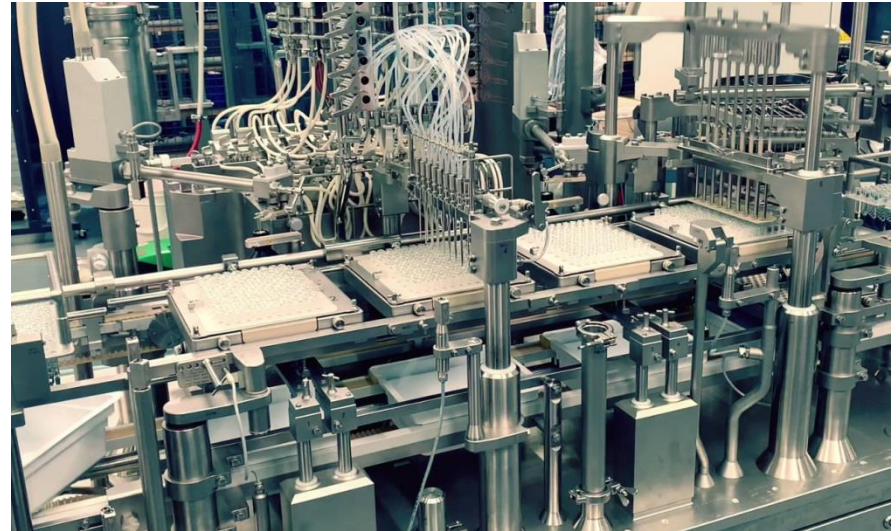
3 high-speed filling lines:

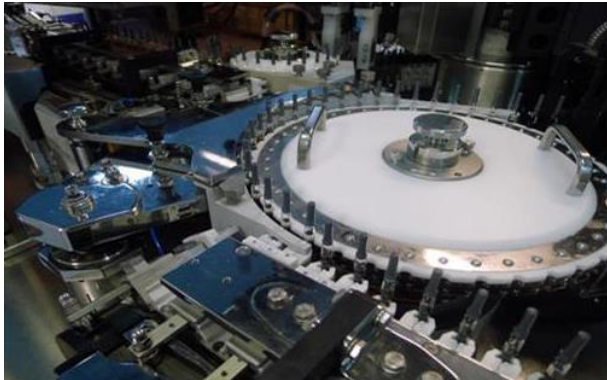
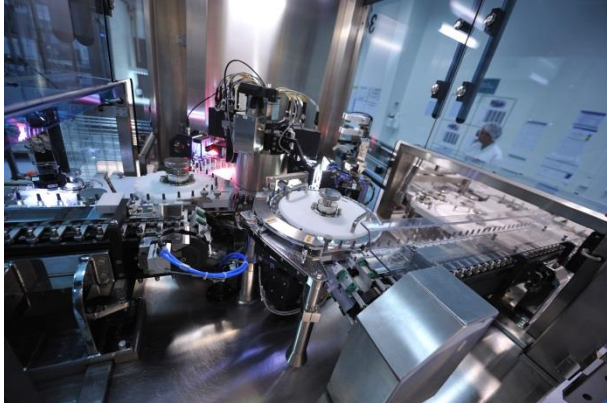
Etna line : Fraxiparine™ + Arixtra™ + WFI + MonoEmbolex™

Stromboli line : Fraxiparine™ + MonoEmbolex™

Vesuve line : 2020

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





3 inspection lines:

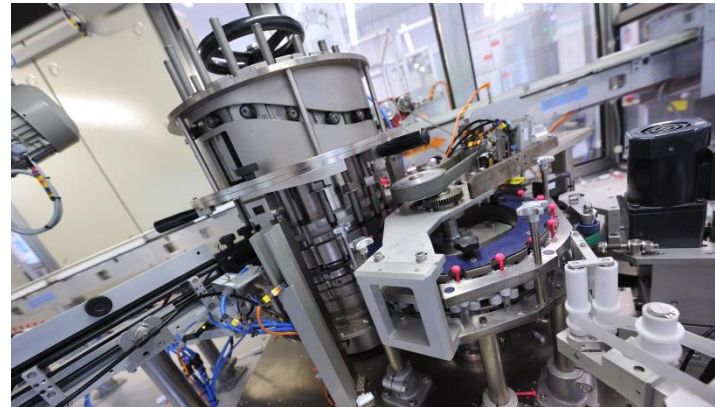
- **Etna line (automatic):** Fraxiparine™ Arixtra™ Monoembolex™
- **Line 24 Maewa (automatic):** Fraxiparine™, Arixtra™ & diluants
- **Line 20 (semi-automatic):** Fraxiparine™
- **Vulcain line (automatic):** 2020

Fraxiparine™

- L27
- L29
- L23
- L5

Arixtra™ & MonoEmbolex™

- L16
- L17
- Japon



The new quality control laboratory has been launched in 2017: quality control laboratory activities: from sample receipt to analysis results

2500

M²

3

Divisions (Physical Chemistry, Microbiology, Packaging items control)



WAREHOUSE

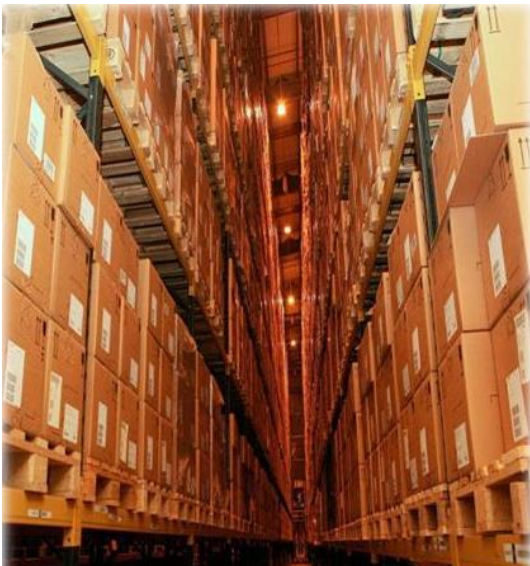
15
Meter high

3
Teams

7000
pallets

1
Class C room for sampling
operations

15-25
Degree
(controlled temperature)

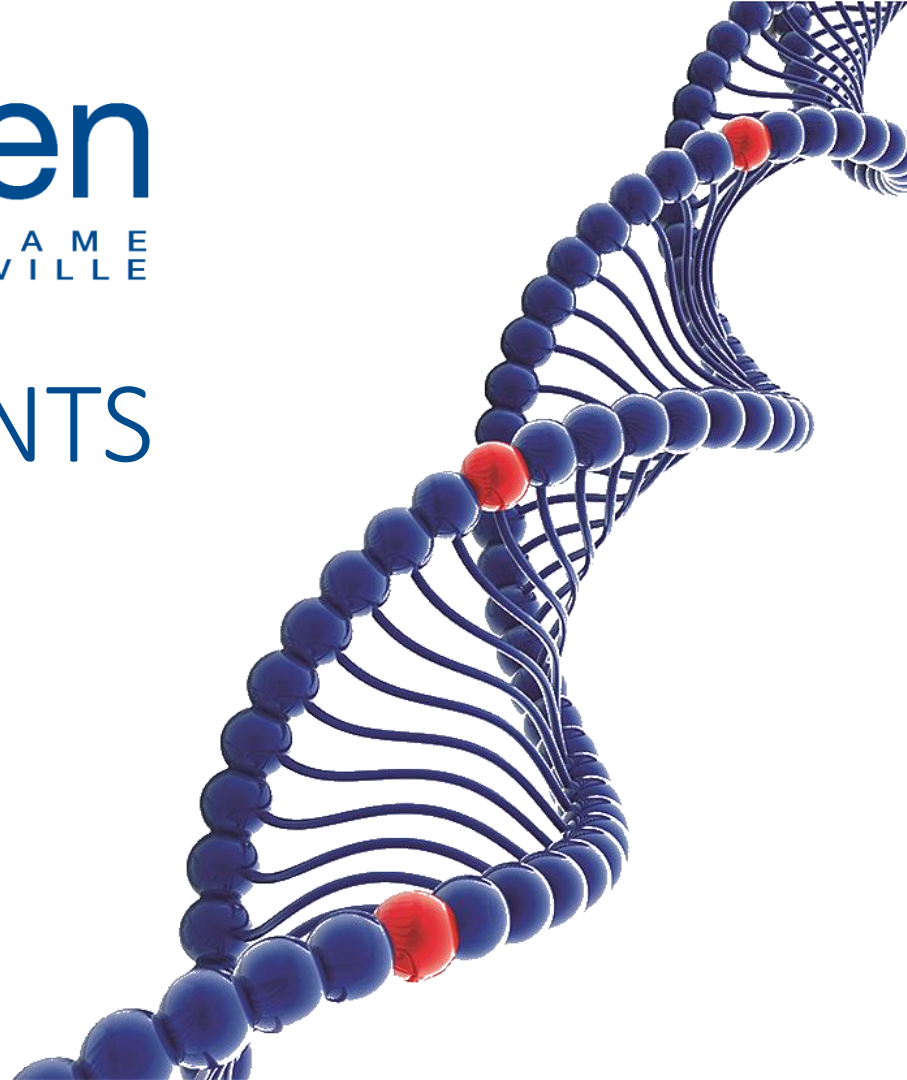




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OUR COMMITMENTS



Healthcare. We Care.

- 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





Investment 3,2 M€
Invested for the environment
since 2010



79%
reduction from
2010 to 2018



0 waste buried since 2012
Reduction of **33 %** from 2010 to 2018
82% of waste is recycled



48%
reduction
from 2010 to
2018