

COMPANY PRESENTATION

2015



CBC GROUP





WHO & WHERE WE ARE



Procos, owned by the Japanese CBC Co., Ltd. Group, is an Italian company which leads in developing, manufacturing and worldwide marketing Active Pharmaceutical Ingredients for human and veterinary use.

Our production site, sizing over 100.000 m², is located in NW-Italy, at 40' distance from Milano and 30' from Malpensa airport.





- 1945** Foundation
- 1952** GMP authorization by Italian AIFA (Ministry of Health)
- 1982** First inspection by American FDA
- 1990** Management Buy-out
- 1991** Construction of the new plant starts
- 2001** Implementation of SAP; ISO 14001 certification
- 2006** Acquisition by CBC Co. Ltd.
- 2007** Establishment of N-America branch office in Commack, NY
- 2008** Site accreditation by Japanese PMDA
- 2009** Set up of E-Europe branch office in Bratislava, Slovakia
- 2010** Authorization of Kilo-lab for small scale GMP production
- 2011** Complete revamping of finishing department RP
- 2012** OHSAS 18001 certification; setup of C-Europe branch office in Munich, Germany
- 2013** Authorization of MiniLab for high potent gram scale GMP production
- 2014** Starting with "R10" new facility building



114 ■ Production

27 ■ R&D

33 ■ Quality

11 ■ HSE

25 ■ Engineering & Maintenance

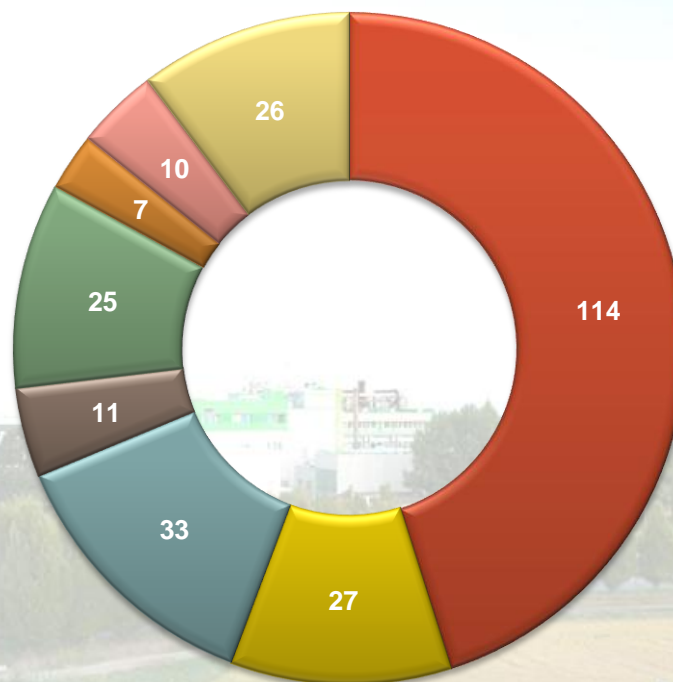
7 ■ Purchasing

10 ■ Sales & Marketing

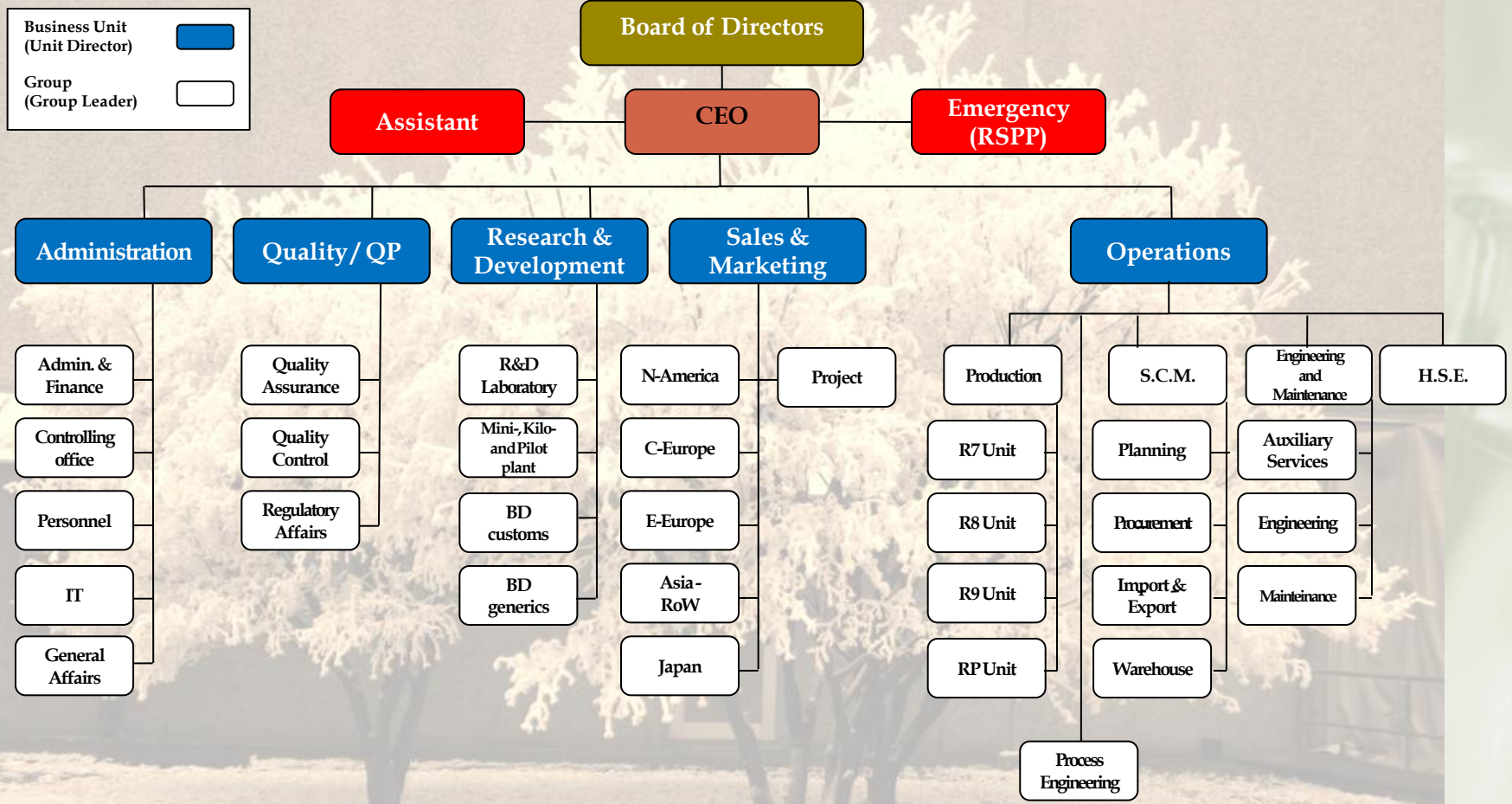
26 ■ Administration & General services

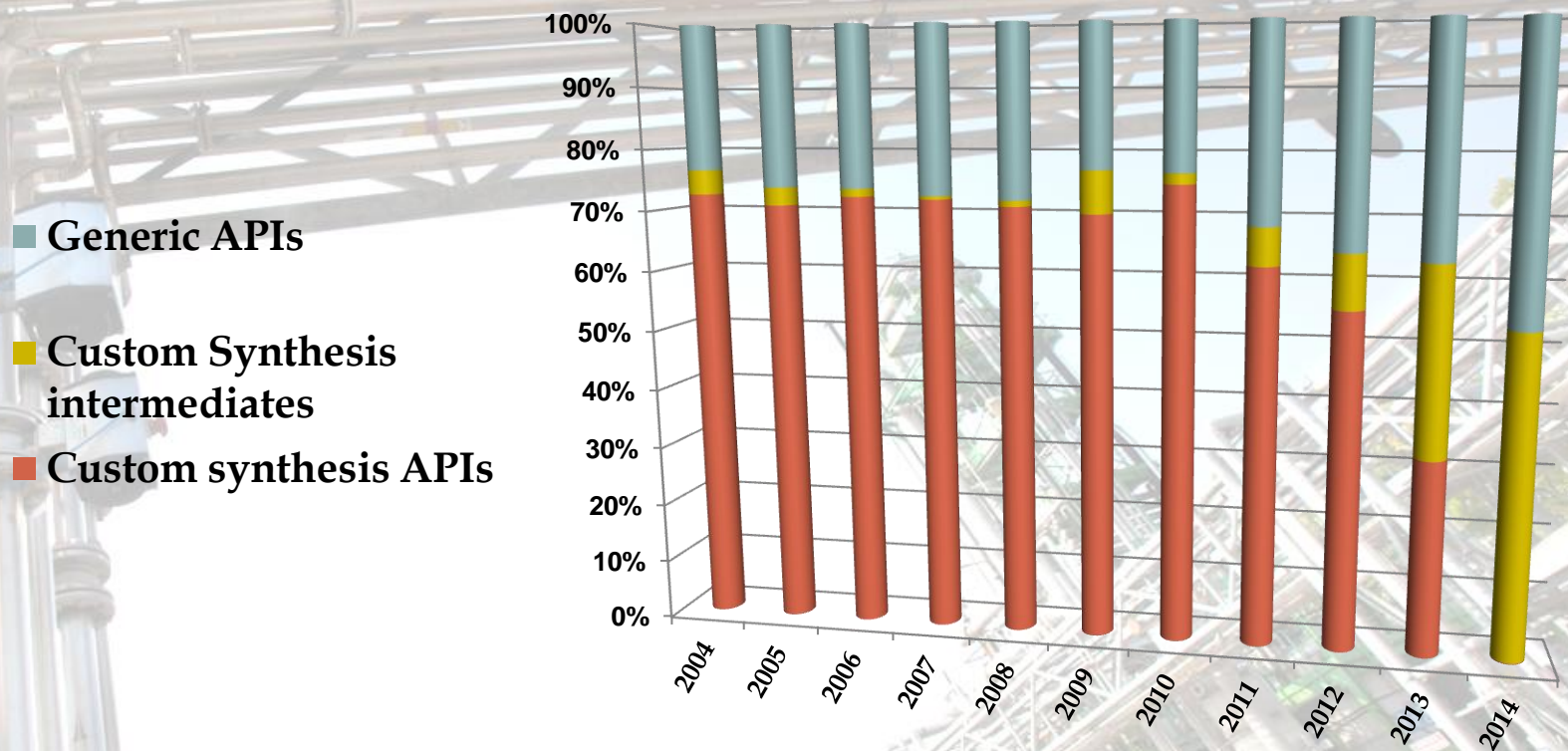
253 Total *

* 6 at Sales & Marketing branch offices



Operational on 3 shifts, 5 days out of 7





2014 sales € 52.4 M

**53% custom synthesis (0.3% APIs + 99.7% intermediates)
47% generics**



➤ **Regulatory track with Health Authorities (no critical remark by any):**

- AIFA authorized since 1952

Last GMP inspection for human use in October 2013

for vet. use, by MinSal, in June 2014

EU-DMF for 34 products (including 4 veterinary APIs)



- FDA authorized since 1982

Last inspection in August 2013

US-DMF for 18 products (including 3 veterinary APIs)



- PMDA authorized since 2008

Inspection and site accreditation in September 2008

J-DMF for 5 products (including 1 veterinary API)



➤ **Other certifications:**

- Environmental ISO 14001 since 2001

- Occupational Health and Safety OHSAS 18001 since 2012





High pressure hydrogenation

Multi-Catalytic hydrogenation

Enantioselective hydrogenation

Hydrazine chemistry

Chiral chemistry

Metal hydride reduction

Epichlorohydrin chemistry

Cyanide chemistry

Sulfide chemistry

Oxidation

Enzymatic resolution

Cryo-chemistry

Homogeneous catalysis

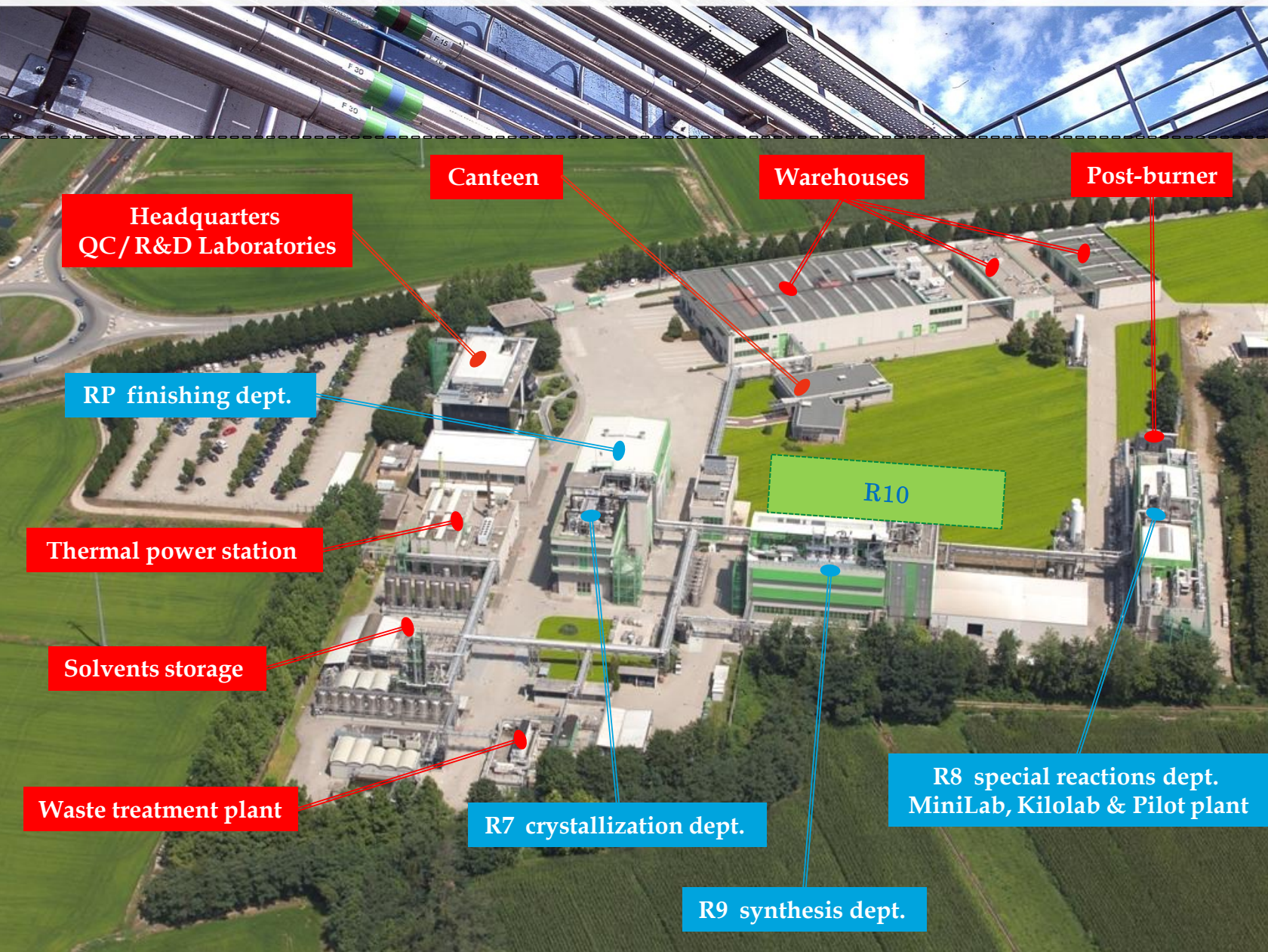
Lithiation

Suzuki coupling

Reformatsky reaction

Halogenation

Organo-metallic chemistry



Headquarters
QC / R&D Laboratories

Canteen

Warehouses

Post-burner

RP finishing dept.

R10

Thermal power station

Solvents storage

Waste treatment plant

R7 crystallization dept.

R8 special reactions dept.
MiniLab, Kilolab & Pilot plant

R9 synthesis dept.



➤ Analytical:

- Methods development, transfer and validation
- Reference standards characterization and qualification (NMR, GC-MS, UPLC-MS)
- Polymorphism (X-Ray, DSC, FT-IR)
- Stability studies
- Suppliers' qualification

➤ Chemistry-related activities (non-GMP):

- Patent scenario and cost evaluation (internal database)
- Process familiarization, optimization and innovation (HEL Poly-BLOCK™ parallel synthesis)
- Flow-sheet definition and scale-up activities
- Crystallization studies
- Synthesis of impurities, including genotoxic ones
- Safety studies (Mettler RC1™, Systag RADEX™ calorimeters)



➤ Mini-lab

- Glove-box (6 mt) / 4 chambers
- OEB 4 (HPAPI)
- Batch size 10 ÷ 200 g
- Temperature range $-80^{\circ} \div +200^{\circ} \text{ C}$
- Chromatographic chamber

➤ Kilolab

- 150 l capacity by glass and hastelloy reactors
- Batch size 0.1 ÷ 5 kg
- Temperature range $-80^{\circ} \div +160^{\circ} \text{ C}$
- Isolation by centrifuge or Buchner filters
- 40 l chromatographic column
- Static dryer
- Physical treatment by hammer mill and jet-mill

➤ Pilot plant

- 2.500 l capacity by stainless steel, glass-lined and hastelloy reactors
- Batch size 5 ÷ 50 kg
- Temperature range $-80^{\circ} \div +160^{\circ} \text{ C}$
- Isolation by centrifuge
- Static dryer
- 400 l autoclave



➤ Industrial plant

- 320.000 l reactors capacity, by stainless steel, SAF and glass-lined (excluding 140.000 l ancillary equipment capacity)
- Batch size 50 ÷ 1000 kg
- Temperature range -50° ÷ +160° C
- Authorization for storage and handling of hazardous materials
- Isolation by vertical / horizontal centrifuges or filter-dryer
- Static and thin-film evaporators
- 6.000 l autoclaves capacity
- Physical treatment by hammer mill, cyclone mill and jet-mill
- Manufacturing units:
 - ✓ R7 crystallizations
 - ✓ R8A high pressure hydrogenations
 - ✓ R8B hazardous chemistry and distillations
 - ✓ R9 large volume general synthesis
 - ✓ RP finishing by drying and milling / micronizing



Capacity growth:

- 4'000 m² , 5 floors
- 8 production modules/lines
- 12'000 liters GL & SUS reactors in 3/8 modules
- From actual 320 m³ up to 450 m³ as total capacity

Technology expansion:

- Innovative challenge in 5/8 modules

Operations start from Q3 2015





R10 NEW FACILITY





➤ **Founded in Tokyo in 1925 as *Doi Utaro Shoten*; renamed *CBC Co., Ltd.* in 1999**

➤ **2013 figures, as of 2014 March 31st:**

2'902 employees (435 as *CBC Co., Ltd.*)

turnover ¥ 135'682 M (€ 955 M or \$ 1'314 M)

income before taxes ¥ 2'925 M (€ 20,6 M or \$ 28,3M)

➤ **Sales and distribution offices in 15 countries**

➤ **Manufacturing of:**

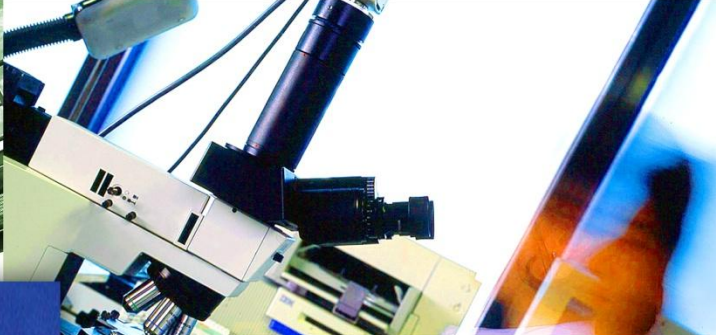
➤ **plastic housing at *CBC Ings* in Thailand (Bangkok), Japan (Mishima, Osaka) and China (Changshu, Dongguang, Tianjin);**

➤ **optical lenses at *CBC Optronics* in China (Beijing) and Bangladesh (Chittagong);**

➤ **pharmaceutical APIs at *Procos SpA* in Italy (Cameri, NO)**

➤ **specialties for agriculture at *Intrachem Bio Italia SpA* in Italy (Grassobbio, BG)**

➤ **Investment in Ticinum Lab, Pharma Research Center, based in Italy (Novara)**



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