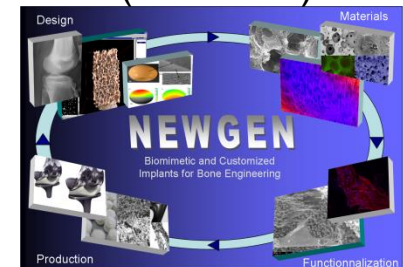


GENERAL PRESENTATION

- **Complete denomination:** Produits Chimiques Auxiliaires et de Synthèse (**PCAS**)
- **Location (city, country):** Paris region (France)
- **General Manager:** Vincent TOURAILLE
- **Contact person in NEWGEN:** Dr. Karine SALIM
- **Working Group involvment:** WG1
- **Staff:** Chemical company founded in 1962 with 950 people in 2013 and 8 production sites (Pharman Cosmetics, Parfum....)
- **Research topics:** Industrial Manufacturer at tons scale under GMP and ISO 9001
- **Products:** Pharmaceutical Ingredients (APIs) , Biomaterials, Biodegradable Polymers, Functional excipients and other Chemical entities
- **Researchers expertises:** industrial R&D , Organic Chemistry, Polymeric Chemistry, Biocatalysis

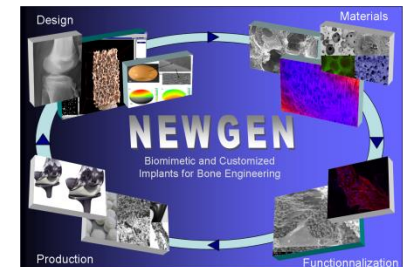
BIOMATERIALS/NEWGEN TOPICS

- Polymers for Drug Delivery & Medical Devices:
 - EXPANSORB® , Biodegradable polymers product line : PLA / PLGA, PLGA-PEG and other derivatives (catalog & screening kit for research and industrial production) used :
 - Controlled release formulation of injectable /implantable drugs (weeks to months)
 - Biomedical devices, Vaccines
 - Custom Polymers development for API vectorisation including nucleic acids
 - Tailored PLA/PLGA
 - Functional excipients: i.e Glycofurol (Solvent)
 - GMP Chemicals for medical devices like diabete monitoring system
- Solid Supports:
 - ChemMatrix® resins catalog: Solid Support for peptide synthesis
 - Custom production of purification media (resins) for therapeutic proteins (ie: mAbs)
 - Amberjet (s): used for peptide functionalisation



PCAS'input

- Provider of Biodegradable polymers based on PLA and PLGA and use of new monomers (i.e TMC, Caprolactone...)
- Fine-tuning of existing polymers
- Development of new polymers (under CDA)
- Scale up and validation batches production for trials
- production under GMP at industrial scale
- Support for regulatory affaire and registration
- Keys words: Biodegradable, resorbable Bulk polymers, Sustained release, Drug delivery, Manufacturing under GMP, Scaleup



FACILITIES

- Former Ipsen site located near Avignon
- Acquisition by PCAS in 2001
- 150 employees

- **Last FDA inspection: 2013**
- **Last EU National Agency inspection: 2014**

- Total reactor capacity : 100 m³ (up to 10,000 L)
- Chemical development team
- Pilot unit and Kilo-Lab

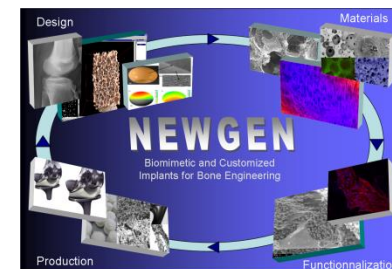
- Dedicated Biocatalysis Platform
- Dedicated Polymers workshop
- Large scale Ethylene oxide capabilities
- Regulatory affairs team



Examples of products made in Aramon:

- **PLA/PLGA pharma polymers**
- **Glucose sensor production**
- Troxerutine
- Divalproex Na...

....



COST Action MP1301

Products line:

- Proprietary Biodegradables polymers - Catalogue
 - Know-how of 17 years on PLGA
 - **PCAS trade name** of PLGA & PLA polymers: **Expansorb®**
 - 34 references with a Kit-Box for R&D screening
 - Several are already used in the formulation of drugs in the market
 - Production under cGMP & US DMF type IV (Excipient)
- PLA/PLGA and dérivatives with custom specifications
- Polymers for Nucleic Acid vectorisation...

Production Scale:

- ✓ GLP batch size up to 1.3 kg → développement
- ✓ ICHQ7 compliant batch sizes 4-7 kg
- ✓ Future Scale : ICHQ7 compliant batch sizes 36-40kg

