## PERSONAL INFORMATION Marco Dieci

Via Renzo e Ildebrando Bocchi, 4 – 43126 Parma, Italy
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marco.diecim@gmail.com

Sex Male | Date of birth 25/02/1968 | Nationality Italian

## OCCUPATIONAL FIELD

BIOPHARMACEUTICAL MANUFACTURING, BUSINESS; FINANCE AND OPERATION MANAGEMENT Marco Dieci

## WORK EXPERIENCE

(2018- to date) Chief Executive Officer (CEO)
Holostem Terapie Avanzate S.r.l. (https://www.holostem.com)
- Business, Finance and Operation Management

Business or sector Business, Finance and GMP Operation Management

(2015 - 2017) Head of GMP Biopharmaceutical Phacility Unit
Ospedale Pediatrico Bambino Gesù (www.ospedalebambinogesu.it/)
- Business, Finance and Operation Management.
- Certification of the GMP Biopharmaceutical Facility for Cell & Gene Medicinal Products

Business or sector GMP pharma manufacturing (CMO)

(2013 – 2015) Chief Executive Officer (CEO)
Xellbiogene S.r.l.
- Company start up activity as a CEO (shareholders: Ospedale Pediatrico Bambino Gesù and Università Cattolica Sacro Cuore)

Business or sector Business, Finance and GMP Operation Management

(2012 – 2015) Executive Director CMO
Ospedale Pediatrico Bambino Gesù (http://www.ospedalebambinogesu.it/home)
- Project management for the creation and operation of a new Research Centre (6.000 $m^2$), including a GMP biopharmaceutical facility (Project design, realization and cost management)

Business or sector Contract Manufacturing Organization (CMO) for Biopharmaceutical

(2008 – 2012) Operations Director
MolMed S.p.A. (www.molmed.com)
- Head of Operation & Development Units

Business or sector Medical Biotechnologies

(2004 – 2008) Executive Committee Member
MolMed S.p.A. (www.molmed.com)
- Member of the Board of Directors

Business or sector Medical Biotechnologies

(2003 – 2004) Quality Assurance & Regulatory Affairs Director, Qualified Person
MolMed S.p.A. (www.molmed.com)
- Head of QA & RA and Qualified Person

Business or sector Medical Biotechnologies

(2002 – 2003) Technical Director (Qualified Person)
MolMed S.p.A. (www.molmed.com)
- GMP site Certification obtained ad Qualified Person

Business or sector Medical Biotechnologies

(2001 – 2003) Quality Assurance Manager
MolMed S.p.A. (www.molmed.com
- Head of Quality Assurance

Business or sector Medical Biotechnologies

(1999 – 2001) Quality Assurance & Quality Control Manager
Lameplast Group S.p.A. (www.lameplastgroup.com)
- Head of Quality Assurance and Quality Control Units

Business or sector Medical Biotechnologies

(1998 – 1999) Quality Assurance Assistance
Chiesi Farmaceutici S.p.A. (www.chiesi.com)
- Quality Assurance and Quality Control

Business or sector Pharma

(1996 – 1998) Quality Control GXP Monitor
Chiesi Farmaceutici S.p.A. (www.chiesi.com)
- Quality Assurance Quality Control

Business or sector Pharma

(1996 – 1998) Research Fellow
University of Parma – Department of General Chemistry
- Analytical instrument: HPLC, GC-FTIR, GC-MS, HPLC-MS

Business or sector Analytical Research

## EDUCATION AND TRAINING

| | | |
|---|---|---|
| 2014 | Qualified Person - Manufacturing of Advanced Therapy Medicinal Products - Qualification Certificate | EQF 8 |
| 2002 | Technical Director Pharma Factory – Qualification Certificate | EQF 8 |
| 1995 | State Exam - Qualification certificate to practice as a Chemist | EQF 7 |
| 1987-1995 | *Laurea Magistrale* in Chemistry<br>University of Parma – Course of Mathematics, Physics and Natural Sciences (Italy) | EQF 7 |
| 1982-1987 | *Maturità Scientifica* (School-leaving certificate)<br>*Liceo Scientifico* "G. Marconi", Parma (Itally) | EQF 4 |

## PERSONAL SKILLS

Mother tongue: Italian

Other language(s)

| | UNDERSTANDING | | SPEAKING | | WRITING |
|---|---|---|---|---|---|
| | Listening | Reading | Spoken interaction | Spoken production | |
| English | C2 | C2 | C2 | C2 | C2 |

Levels: A1/2: Basic user - B1/2: Independent user - C1/2 Proficient user
Common European Framework of Reference for Languages

Communication skills
- good communication skills gained through my experience as CEO and teacher at several training courses even as Free contractor at University (San Raffaele and Carlo Cattaneo-LIUC)

Organisational – Management skills

- Leadership (currently CEO of a Biotech Company devoted to gene therapy and regenerative medicine).
- CEO of a Company and Executive Director of a CMO
- Project Management (realization in a12-month period of a Research Centre of 5.000 $m^2$, including a GMP facility and management of the relevant budget amounting to Euros 25M).
- Resource management.
- Construction supervision, design and layout implementation
- Venture interaction for found raising

Job - related skills

- Evaluation and optimization of production processes and implementation of cost-containment programs;
- GMP Authorization for manufacturing of advanced therapy sterile medicinal products (gene and cell therapy medicinal products) and biotech products;
- Production of differ type of virus (RVV, LVV and AAV) and different type of biotech products (protein, recombinant protein, Ab and mAb);
- Production process validation (biotech, cell therapy and gene therapy).
- Production process scale-up.
- GMP/GLP management following European and FDA standards.
- Management of validation procedures for equipment (production and QC) and software.
- Implementation of control plans on production documents and quality control (batch and CoA review).
- Management of quality systems (UNI EN ISO 9000).
- Compliance (management of audits, inspections; due diligence).
- Plant management.
- Regulatory affairs: preparation of clinical trial dossier for submission in Europe (IMPD) and US (IND); regulatory strategies; CE marking approval for medical devices.

Computer skills

- Excellent command of Microsoft Office™ tools, e-mail and collaboration.

Driving licence

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