

Alicia Roda Camporeale – Condensed CV

1. PERSONAL INFORMATION

Tel number +59892161116
Nationality: Uruguayan and Italian

2. BACKGROUND

Alicia is a seasoned senior leader recognized for driving and sustaining organizational change through strategic planning, talent development and execution to plans. She has demonstrated success in leading through times of significant change including high growth, critical product introductions, optimization/remediation programs, and quality system upgrades. She has comprehensive knowledge of FDA and global regulations with the ability to navigate businesses between operation and regulation.

3. EDUCATION

- **Chemical Engineer.** Universidad de la República Oriental del Uruguay- UDELAR (University of the Republic of Uruguay). Six- year full-time course. 1991-1997
- **MBA-** Master in Business Administration. IEEM, Montevideo. 2018
- **Lean Six sigma Black belt** certification. HLT Network. 2021
- **Lean Six sigma Green belt** certification. TUV. 2019
- **ISO 13485 Qualified Quality Auditor** LSQA (Quality Austria). 2009
- Quality Auditor. LATU/ÖVQ. 2002
- Umweltmanager (Environmental Manager). LATU/DGQ. 2000
- Evaluator coordinator for the Ibero-America Quality Award. Fundación Iberoamericana de Gestión de Calidad (FUNDIBQ). 2000
- Quality Manager. LATU – DGQ.1997
- Quality Specialist. UNIT (Uruguayan Standardization Institute). 1996

4. PERSONAL SKILLS

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|----------------------|-----------------------------------|
| ✓ Leadership | ✓ Conflict Management |
| ✓ Decision Making | ✓ Team builder |
| ✓ Efficiency | ✓ Self-started and self-motivated |
| ✓ Commitment | ✓ Social intelligence |
| ✓ Negotiation | ✓ Courage |
| ✓ Strategic planning | |

5. WORK EXPERIENCE

- 2015- 2025 **Integer Montevideo /CCC del Uruguay. Position: Quality Sr. Manager.**
- Leader of the Quality team with 100+ reports.
 - Main responsible for the Quality System and Regulatory compliance at a Medical Device Industry for a Class III medical device (applicable standards: FDA Regulations (QSR, with 5 PMA products), ISO 13485, ISO 14971, ISO 9001, ISO 11135-1, Medical Device Regulation (MDR).
 - Solid experience in negotiations with customers and suppliers.
 - Problem solving, improvement projects leader.

- Counterpart during transfer of Manufacturing processes to Tijuana Site, within Integer (project executed between 2018-2019 and involved a team of 20+ associates from the two sites).
- Responsible for evaluating the KPIs and the process monitoring statistical data, defining and leading improvement actions.
- Team development focusing in enhancing their skills.

2003- 2014 **CCC del Uruguay. Position: Validation Assistant Manager.**

- Project leader for the validation of critical processes, defining optimal parameters to improve efficiency and assuring stability of processes (projects of over USD 1.000.000 involved).
- Designer and Manager of the Validation Master Plan of varied products and approval of the generated documentation for the manufacturing processes and controlled areas monitoring (particle and microbiological monitoring).
- Supervisor of the Calibration Plan compliance.
- Process owner of the sterilization process (ETO).

2006- 2014 **CCC del Uruguay. Position: Quality Assistant Manager.**

- Main responsibilities include: Quality compliance at a Medical Device Industry for a Class III medical device (applicable standards: FDA Regulations (QSR), ISO 13485, ISO 14971, ISO 9001, ISO 11135-1, Medical Devices Directive (AIMDD)). In charge of: management of supplier audits and evaluations, administration of management reviews, management of internal and third-party audits. Reviewer of non conformities, Corrective and Preventive Actions, engineering change orders (including notification to the Competent Authorities).
- In charge of new regulation compliance analysis (local regulation and CE mark related).
- In charge of managing the Validation Monitoring Plan.
- Responsible for evaluating the quality indicators and the process monitoring statistical data, defining and leading improvement actions.

2002- 2003 **CCC del Uruguay. Position: Head of Manufacturing Sector.**

Main responsibilities include: Planning of the manufacturing activities, supervision of associates, Maintenance Plan Management and Calibration Plan management, sterilization process definition and monitoring.

2000- 2015 **Third-party Auditor.** Details in annex I

1997-2002 **IBERSIS/SOLUZIONE. Senior Consultant.**

Main responsibilities: design and development of Quality and Environmental Management Systems in various companies.
First Environmental impact assessment for a Cellulosic Plant in Uruguay (2001. For Ence). Details in annex II.

2002-2003 **IBERSIS/SOLUZIONE. Position: Business Developer in Argentina, Chile and Uruguay.**

Results:10 projects sold in Uruguay, 1 in Argentina and 2 in Chile

1996-1997. **COUSA. Position: Quality Engineer.** Main responsibilities: design and implementation of the Quality System.

6. SPOKEN LANGUAGES

- Spanish: Native
- English: Full professional proficiency.

7. AWARDS

- Academic recognition in the MBA course

8. ANNEX I: Third party audits

COMPANY	YEAR	LENGTH	STANDARD	AS	TYPE OF AUDIT	CERTIFICATION BODY
Banefe Banc (Chile)	2000	2 days	ISO 9001	Observer	Previous visit	AENOR
Banefe Banc (Chile)	2000	2 days	ISO 9001	Observer	Certification	AENOR
Tramil (Construction)	2004	2 days	ISO 9001	Observer	Certification	LATU-Quality Austria (ÖQS)
AT-Gen (In vitro kits)	2009	3 days	ISO 13485	Expert	Previous visit	N/A
TABIRAL	2009	3 days	ISO 13485	Auditor	Certification	LATU-Quality Austria (ÖQS)
TABIRAL	2010	2 days	ISO 13485	Auditor	Certification	LATU-Quality Austria (ÖQS)
E-Medical	2011	1 day	ISO 13485	Auditor	Certification, first part	LATU-Quality Austria (ÖQS)
TABIRAL	2011	2 days	ISO 13485	Auditor	Certification follow up	LATU-Quality Austria (ÖQS)
GOMSIL	2011	2 days	ISO 13485	Auditor	Certification	LATU-Quality Austria (ÖQS)
Técnicos Asociados (Mar del Plata, Argentina)	2012	2 days	ISO 13485	Auditor	Certification	LATU-Quality Austria (ÖQS)
E-Medical	2012	2 days	ISO 13485	Auditor	Certification	LATU-Quality Austria (ÖQS)
TABIRAL	2013	2 days	ISO 13485	Auditor	Re-Certification	LATU-Quality Austria (ÖQS)
E-Medical	2014	1 day	ISO 13485	Auditor	Certification follow up	LATU-Quality Austria (ÖQS)
ATGen Diagnóstica	2014	2 days	ISO 13485	Auditor	Certification	LATU-Quality Austria (ÖQS)
TABIRAL	2014	1 day	ISO 13485	Auditor	Certification follow up	LATU-Quality Austria (ÖQS)

9. ANNEX II

CLIENT	PROJECT	YEAR
EUFORES	Responsible for the authorization application for the effluent treatment of a chipper facility at the Environmental Agency of Uruguay (DiNaMA). Technical Responsible at the Environmental Agency of Uruguay (DiNaMA) for the effluent treatment of a chipper facility.	2002
ENCE -Spain	Environmental Impact Assessment (EIA) for “Celulosas de M’Bopicuá” (Cellulosic plant), approved by the Environmental Agency of Uruguay (DiNaMa).	2001-2002
REPSOL YPF (Argentina)	GAP analysis using FUNDIBQ (Ibero-American Quality Foundation) Quality Award model.	2001
CODELCO – Andina -(Chile)	Design, development and implementation of an environmental and quality system according to ISO 14001 and ISO 9001.	2000
MASISA Argentina S.A. (Buenos Aires and Concordia)	Design, development and implementation of a quality system according to ISO 9001	2000-2001
VIÑEDOS Y BODEGA FILGUEIRA	Design, development and implementation of a quality system according to ISO 9001	2000-2002
ISBEL	Design, development and implementation of a quality system according to ISO 9001	2000-2001
TECHINT SACI	Design, development and implementation of a quality system according to ISO 9002	1999
Repremar S.A.	Design, development and implementation of a quality system according to ISO 9002	1999
Repremar Logistics	Design, development and implementation of a quality system according to ISO 9002	1999
Fábrica de elementos de hormigón armado de UTE	Design, development and implementation of an environmental and quality system according to ISO 14001 and ISO 9001.	1998-1999
ALUR S.A.	Design, development and implementation of a quality system according to ISO 9001	1997-1998
Simoneschi S. A. (Argentina)	Gap analysis according to ISO 9002	1997
CCC del Uruguay	Design, development and implementation of a quality system according to EN46001	1997-1998
SUAT	Design, development and implementation of a quality system according to ISO 9002	1997-1998
SAP Implementation Division IBERSIS	Design, development and implementation of a quality system according to ISO 9002	1997