

# Garó A Mimaryan

M.S. | M.Sc. | PMP® | RAC-US | RAC-Devices

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## Regulatory Affairs Project Management Professional

Accomplished and certified Regulatory Affairs (RAC-US, RAC-Devices) and Project Management Professional (PMP) with 10+ years of experience translating performance and clinical data into actionable regulatory strategies to support market access and program development across the healthcare industry. Extensive experience compiling and reviewing regulatory submissions for the U.S. FDA and EU Notified Bodies. Led Agile and hybrid cross-functional teams across the U.S. and Europe to align project execution with organizational objectives, support audit readiness, and ensure end-to-end regulatory compliance throughout the product lifecycle, including combination products, medical devices and in vitro diagnostic devices. Demonstrated skills:

### Skills:

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- Adaptive (Agile), Predictive (Waterfall) and Hybrid Methodologies
  - Strategic Planning, Project Execution, Monitoring and Reporting
  - Business Acumen, Data Analytics, Earned Value Management and Emotional Intelligence
  - Combination Products: (21 CFR part 3.2(e), 21 CFR part 3.7)
  - Companion Diagnostics and In Vitro Diagnostic Devices and Premarket Approval (PMA) pathways
  - Quality Management Systems (GMPs): (21 CFR part 820, ISO 9001, ISO 13485)
  - Clinical Investigations (GCPs) and Risk Management: (ISO 14155, ISO 14971)
  - Digital Therapeutics and (SaMD) Software as a Medical Device: (IEC 62304)
  - Regulatory Compliance and Surveillance: (MDR 2017/745, IVDR 2017/746)
  - Abbreviated, Special, Traditional 510(k) Premarket Notifications and De Novo authorization requests
  - Design Controls, Design History File (DHF), CE-Marking, and Technical File Management (**Veeva Vault**)
  - Statistical Analysis Planning and Interpretation of Data and Statistical Methods: (ISO 3951, ISO 5479)
  - Data Cleaning and Validation, Hypothesis Testing, Study Design and Sample-size Calculations
  - Descriptive & Inferential Statistics, Regression & Survival Analysis, Monte Carlo Simulation (**IBM SPSS**)
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### Experience:

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#### Regulatory Affairs Manager

Teva Pharmaceuticals Inc., Parsippany, New Jersey

June 2021 – September 2024

- Led a cross-functional team within a Hybrid project framework to provide strategic oversight of an experimental drug-device combination product achieved 99% on-time milestone completion, reduced review timelines by 20%, and ensured continued regulatory compliance.
- Provided regulatory guidance to Research & Development teams to conduct regression analysis of past stability data, which helped secure FDA-approved shelf-life extensions and led to \$275,000 in cost savings.
- Directed a cross-functional team using a Waterfall project management approach to optimize change control reviews for drug-medical device combination products and provided regulatory and statistical guidance on labeling updates to ensure regulatory compliance and achieved 99% on time implementation.

## Regulatory Project Manager

Colgate & Palmolive Company, New York, New York

January 2020 – February 2021

- Mobilized a cross-functional team using a Hybrid project management method to qualify an alternate supplier for a drug-device combination product, increasing supply availability by approximately 80% and delivering \$250,000 in annual cost savings while maintaining regulatory compliance.
- Authored and implemented a Data Governance Project Charter engaging five (5) stakeholders to standardize controls across nine (9) enterprise data domains, strengthening data quality, compliance, and data integrity to support statistical analysis and data-driven program development decisions.

## Regulatory Affairs Project Manager

Sandoz, a Novartis Division, Princeton, New Jersey

October 2016 – January 2020

- Managed a cross-functional team using a Hybrid project framework to optimize change control reviews for medical devices and provide regulatory and statistical guidance (ISO 3951 and ISO 5479) on labeling updates and internal audit reviews to ensure regulatory compliance and to achieve 99% on-time implementation.
- Led an Agile development team to compile performance and clinical data for statistical analysis in supporting a Software as a Medical Device (SaMD) Digital Therapeutic by applying IEC 62304 software life-cycle controls and ISO 14971 risk management requirements, resulting in U.S. FDA De Novo authorization.

## Certifications:

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- **Project Management Professional (PMP)<sup>®</sup>**  
Project Management Institute ([Digital Badge](#))  
Credential ID Number: 4192817
  - **Regulatory Affairs Certifications (RAC)**  
RAPS Institute (RAC–US: [Digital Badge](#) & RAC–Devices: [Digital Badge](#))
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## Education:

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- **Certificates in Applied Statistics & Project Management**  
Cornell University, Ithaca, New York
  - **Master of Science in Bioscience Regulatory Affairs**  
Johns Hopkins University, Baltimore, Maryland
  - **Master of Science in Biostatistics**  
New York Medical College, Valhalla, New York  
**Thesis: Evaluation of Study Designs and Statistical Methods to Establish Bioequivalence**
  - **Bachelor of Science in Biochemistry**  
Ramapo College, Mahwah, New Jersey
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## Affiliations:

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- Project Management Institute (PMI)
- Regulatory Affairs Professionals Society (RAPS)