Silvia Agnoletto

- **Current Role**: EMEA Regulatory Affairs Professional
- **STAR Programme**: Regulatory Affairs
- **Programme Year**: 2024-2025

‘How Silvia Launched Her Regulatory Affairs Career with ECCRT’s STAR Programme’

Before the STAR Programme

I come to regulatory affairs from a background in pharmaceutical sciences. I hold a Master’s Degree in Pharmaceutical Chemistry and Technology from the University of Padua, where my studies covered the full path a medicine travels from molecule to finished product.

For my thesis I moved to KU Leuven in Belgium to carry out research in enteric neuroscience. Working abroad on a laboratory-based project gave me my first experience of an international research environment, and of the standards and rigour that scientific work in that setting demands.

Why ECCRT?

I first came across the STAR Programme on the LinkedIn profiles of several professionals working in the industry, and it stayed with me because of the way it was built: a genuine balance of theory and practice rather than classroom training alone.

That balance was exactly what I was missing: a real opportunity to gain my first experience in the pharmaceutical industry, and to gain it inside a company rather than at a distance from one.

Experience During the Programme

I had the opportunity to join the Johnson & Johnson EMEA Regulatory Affairs Oncology team, working across both the Haematology and Solid Tumour sub-teams on products for multiple myeloma and bladder cancer. My internship included:

- Supporting regulatory activities: **variations, post-authorisation measures, clinical trial applications, scientific advice, and product information updates**
- Assisting in the preparation and review of regulatory documents, including cover letters, application forms, CMC documents, dossier plans, PSURs, and study protocols
- Managing Health Authority reports, helping to draft responses and forecast timelines
- Archiving key documents and maintaining regulatory databases
- Collaborating with cross-functional teams
- Conducting competitor landscape and benchmarking analysis
- Working with regulatory tools such as Lorenz docuBridge, InSight, RIMdocs, TruVault, and IRIS

Where Are You Now?

I secured a permanent position at Johnson & Johnson as an EMEA Regulatory Affairs Professional, supporting two products for multiple myeloma. The internship led directly into the role, in the same therapeutic area and with the same team I trained alongside.

Final Words of Advice

Entering the pharmaceutical industry can be challenging, because it is not something that is fully taught at university. You can finish a degree knowing the science thoroughly and still have very little sense of how a regulatory dossier is actually assembled, or how a team works around it.

This programme gives you the chance to gain those insights directly from professionals in the field, and to launch your career in Regulatory Affairs through the internship. It puts you inside the work rather than beside it.

It is also an opportunity to show a proactive attitude, curiosity and a willingness to learn — and to demonstrate the value you can bring to a team. That, more than anything else, is what carries you from the internship into a role.