



**ORION GXP  
CONSULTING**

# Our People, capabilities and strengths

We aim to provide our clients with expertise, assistance, and an in-depth understanding of the healthcare industry.



# Our Services

## QMS development and Licensing support

We assist clients in expanding their range of products and launching in new territories by developing the required licensing and QMS requirements. This includes writing new procedures, identifying additional resources and assisting with the necessary licence applications.

## Vendor Management and Audit Services

We have built a strong team of GxP audit professionals with decades of experience in GMDP audits of global pharmaceutical drug substance and drug product suppliers. We can also assist with mock facility inspections and vendor qualification using survey and remote inspection capabilities.

## Regulatory, Pharmacovigilance and CMC Support

We assist clients in providing regulatory and CMC subject matter experts with decades of experience in dossier preparation, compliance reviews, MA applications and dealing with EMA and National Competent Authorities.



# Our Services

## Training and Site support

We work with our clients to ensure that the correct quality culture is embedded in their organisation by training the staff in the core principles of GMP, GDP or GCP. We have detailed step-by-step courses available on a wide variety of Quality, manufacturing and engineering disciplines.

## Import Support and QP Staff Augmentation

One of our main services is providing interim QP services to the pharmaceutical industry. We also provide these experts for short-term consulting projects, troubleshooting and CAPA remediation.

## Distribution Support and RP/RPi Services

For GDP and Distribution we also provide the services of interim RP and RPi to the pharmaceutical industry. We also provide these experts for short-term or long-term consulting projects.

# Our Consulting Team



**Charley Maxwell**

MANAGING DIRECTOR

 [in/charleymaxwell/](https://www.linkedin.com/in/charleymaxwell/)


 [charley@orionxp.com](mailto:charley@orionxp.com)


Charley has over 25 years of industry experience as a QP, RP and Senior Consultant.



**Anne Johnston**

COMMERCIAL QP

 [in/anne-johnston-a9a506209/](https://www.linkedin.com/in/anne-johnston-a9a506209/)


 [anne@orionxp.com](mailto:anne@orionxp.com)

Anne releases Clinical Trial IMPs and Commercial products for some of our key accounts in Ireland.



**Nirmal Tarry**

ASSOCIATE DIRECTOR

 [in/nirmal-tarry-01809221/](https://www.linkedin.com/in/nirmal-tarry-01809221/)

 [nim@orionxp.com](mailto:nim@orionxp.com)

Nim heads up our UK operations and is also an RP/RPi looking after EU imports for our UK clients.



**Max Trebilcock**

CONSULTANT

 [in/max-trebilcock/](https://www.linkedin.com/in/max-trebilcock/)


 [max@orionxp.com](mailto:max@orionxp.com)


Max is an all-round Medical Device, GDP, Regulatory Affairs, QMS and licencing specialist.



**Kay Flahive**

CLINICAL QP

 [in/kay-flahive-40b0a995/](https://www.linkedin.com/in/kay-flahive-40b0a995/)


 [kay@orionxp.com](mailto:kay@orionxp.com)

Kay is our analytical and Microbiology specialist. She is also a Clinical QP for one of our key accounts.



**Savanna Edmiston**

Consultant RP/QP

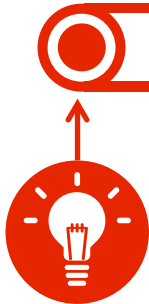
 [in/savanna-edmiston-41966621/](https://www.linkedin.com/in/savanna-edmiston-41966621/)

 [savanna@orionxp.com](mailto:savanna@orionxp.com)

Savanna is one of our RP/RPi in the UK and is QP eligible and will be providing QP support.

# Our History

2021



## Orion GXP Consulting Established in Ireland

Our company was set up initially in Ireland to provide part-time QP/RP support to our pharmaceutical clients.

2022



## Quickly expanded into Regulatory, Med-Dev, Consulting and Training

We quickly established ourselves as a leading service provider of expert knowledge, advice, training and vendor management support across the healthcare industry.

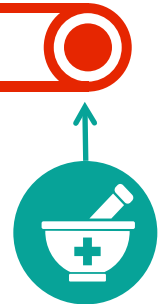
2023



## Expanded services, launched into the UK and grew the team

Throughout 2023 we have been rapidly growing our client base and expanding our service offering also to provide services in the UK.

2024



## MIA for Import and QP batch release

Orion GXP are in final stages of obtaining an MIA & MIA-IMP to provide QP batch release services for clinical sponsors and MAHs.

# Our Quality Policy

## Orion Consulting - Quality Policy Statement

Orion Consulting is focused on enabling access to the European Markets for our clients while maintaining high quality standards and continuous improvement. Quality is a high priority for all employees and is embodied in day-to-day operations.

Orion Consulting operates with the objective of proactively monitoring, reviewing, and enhancing the effectiveness of the PQS and continuously monitoring guidelines and regulations to ensure we utilise best practices and ensure continuing compliance with GMDP and with the terms of the site authorisations.

