QPPV – What is it?

QPPV [Qualified Person for PharmacoVigilance] has a central role in ensuring the company is meeting all of its pharmcovigilance responsibilities and ultimately the safety of the public whilst using the medicine. This transcript from our 'Ask the Experts' session details some of the key areas of responsibility, remit and ability to provide solutions.

Our Experts

- **Sophie Jaillet - Global Head, Vigilances**
  Sophie is responsible for developing and enhancing the vigilance capabilities and services for clients. Within this role, Sophie manages the Vigilance Team to maintain a high standard of client delivery.

- **Fidelma Reid – Senior Director, Vigilance Operations**
  Fidelma provides project management and support on pharmacoviglance pre-authorization projects and post-authorization projects to set up and maintain PV systems in line with applicable regulations.

- **Hayey Marsh – Senior Vigilance Scientist**
  Hayley leads the QPPV Back Office and Regulatory Surveillance team at VCLS, a team that performs all "behind the scenes" activities required to maintain a PV system and ensures internal tools and processes are updated for regulatory purposes and optimised for efficiency.

Question: What is the QPPV's responsibility?

VCLS Answer: Responsibilities are the same for all the QPPVs (and are defined in GVPs) but the most salient ones will depend on the type and size of the company, the number of products you have in your portfolio and the stage of products in development. If you're a small company moving from clinical trials into Phase IV, you are going to be highly involved in clinical trials, but as you move into the post marketing space, you will be focused on setting up your local QP's and your SDEAs (Safety Data Exchange Agreements).
You will be heavily involved in the QMS for the PV and for your organization, so you will be involved in areas such as training, SOP development and looking out for changes in the regulations. If you are working with an existing system, for more mature products, you will be working with your local QPs, drafting and reviewing aggregate reports and handling questions from the regulatory authorities. In conjunction with this you will have an oversight of your medical information function and how that's performing, whether it's in-sourced or not. It really depends on where you are in the life cycle and how many products you are working with and the size of the company. You may be a single operator in a small company, or you may have a QPPV back office to support you in all these activities.

Question: When setting up the PV system, is the Marketing Authorization holder obliged to provide a toll-free number for the end user patient and healthcare professional?

VCLS Answer: This is not covered in the GVP modules. However, in general those reporting lines would be free because you're trying to encourage all adverse events to be reported to

you, whether that's online or on the phone or paper in some cases. You make it as easy as possible for users of your product to report any SAEs or AEs. The GVP modules do not clarify whether those methods incur a payment but as a company you are trying to encourage all information to come in and to make it as easy as possible for the end user to report. It is more a reputational question than anything else, but any costs should be low.
In the EU (including France), the company must provide a reachable contact at the company to answer all the medical information questions. This is often an entry route for notifications of adverse events.

Question: What are the daily activities of a QPPV?

VCLS Answer: The role of the QPPV is to manage and maintain the PV system, so this will mean keeping it up to date with any relevant changes which could include SOP updates that impact the PV system, compliance data, signals, negotiating Safety Data Exchange Agreements (SDEAs) with new partners or reviewing existing SDEAs with existing partners, new vendors impacting the PV System (e.g., safety database).
It varies as it depends on what is going on with your products, this can be anything from interactions with the Regulatory Affairs function, audits and inspections and the internal QA Team. It's a good idea to be up to date in terms of legislation and requirements from Europe but also other jurisdictions as well.

Question: In case of outsourcing the EU QPPV for a company which has MRP DCP products, from which point should the QPPV be trained in product information. Is it from the end of procedure or from the date of national MA approval?

VCLS Answer: The GVP does not define these details, but I would have thought the earlier the new QPPV gets involved, the better. They need to be in place as soon as the product is approved in Europe. I would go for the end of procedure; the earlier the better. The QPPV really needs to understand the product, its development, and the markets in which it is sold and by whom it is distributed. There should not be a delay in getting a new person onboard. The QPPV needs to be nominated at the point of submission of the marketing authorization application, so even before the drug is approved, I think it is a good time for the person who going to take care of the benefit/risk ratio of the product to be aware of everything that concerns the product development.

Question: How are the QPPV and the PSMF linked?

VCLS Answer: The PSMF (Pharmacovigilance System Master File) is the document where the PV system that is in place or that is going to be in place is described. The QPPV is the person who is responsible for setting up and maintaining the PV System, these two are linked in that respect. There is also the aspect of the country where the PSMF is located as well as the QPPV, as these need to be in the same geographical region. If we are talking about a product authorized in Europe, they (QPPV and PSMF) need to be located within the EEA.

Question: When does the PSMF need to be drafted and/or available for the authorities to review. Is it a document that needs to be sent to the authorities? how does it work exactly?

VCLS Answer: The PSMF is a document that needs to be kept up to date at all times. However, the full PSMF is not something you send with your MAA application; it's only submitted when the authorities request it, and within 7 days. Since the PSMF is a description of your PV system, the best approach is to keep it up to date so you can respond to any requests from any authorities within the 7-day deadline. As for the submission, this is done in the manner requested by the authority (this will be stipulated in the request).

Question: What is mandatory requirement for being a QPPV, and what is a 'nice to have'?

VCLS Answer: In the legislation, the GVP Module states that you need to have experience in pharmacovigilance. It is not prescriptive about how much experience you need to have, but it needs to be documented in your CV, along with any PV qualifications, although it does say you need to have access to a medically trained person. A 'nice to have', would be any experience with quality systems, audits and inspections, regardless of the stage of product development. Then it depends on if you are in the "clinical trials moving to post-marketed" stage or are you in the mature product end of things. If you are in the marketed or mature product stage, it'd be useful to have some appreciation for medical information, possibly Safety Data Exchange Agreements and even the more commercial aspects. Which is not the case if it is your first product on the market as you are probably going to need to have more experience in clinical trials, studies, and possible partnerships with other companies you're co-developing the drug with. Definitely pharmacovigilance is the core requisite in all aspects even down to aggregate reporting.

Question: How can a QPPV provide solutions to guarantee or support the integrity of all the PV operations, including the PV network they are managing?

VCLS Answer: QPPV can maintain oversight of the PV system through multiple ways. A global dashboard provides a snapshot of every aspect of the PV system in one place and the QPPV can easily have oversight of the PV system and provide any input where needed.
As a QPPV, you should always ask why? Why is a particular group not being trained? Why is a SOP structured in a certain way? Do not ever be afraid to ask why. Sometimes people do not understand, particularly if they are at the commercial or in the clinical trial end, they do not see why PV might need to be involved. Do not be afraid to ask why while you are reviewing a document (whether it is an aggregate report or a response to go to a regulator, or just an ordinary quality event deviation type report). It is always important to ask why if something does not make sense to you, as you are the person who is ultimately responsible, do not be afraid to ask why or to challenge. If you have the experience outlined earlier, you will be more confident to ask those questions, or to suggest alternative ways but you really need to be on top of things by asking why, it is really important.

Question: With regards to the EMA EU QPPV and the MHRA UK QPPV following Brexit, how are the two systems linked and what are the challenges experienced with the current situation having the UK outside of Europe?

VCLS Answer: As long as you can prove you are compliant to the previous EU GVP legislation and have notified your new national contact person in the UK correctly, there should not be a huge difference. There is a large overlap with the new legislation in the UK and the existing GVP.
Inspectors do understand that companies are adapting to the new situation. It is worth keeping in mind that a local person in the UK is required if you have a product registered in the UK (and the QPPV is not located in the UK). This would be either a UK QPPV or a local contact person who is in the UK and who is aware of all the UK legislation.
The UK legislation has now been finalized, so it will be easier to understand the expectations

Question: Does the Deputy QPPV have to be registered in Eudravigilance?

VCLS Answer: A Deputy QPPV is not a requirement. A back up system is. So this does not necessarily mean you should have one Deputy QPPV who takes over the QPPV's activities when they are not available, but a system in place that allows the provision of back-up. The people who are part of the back-up system do not need to be registered in Eudravigilance as

the back-up to the QPPV. However, as they will need access to the EudraVigilance database they should definitely be registered as individual users.
The contact details of the Deputy QPPV can be included in the PSMF when this is the backup system in place.

Question: Regarding UK market, as part of the QMS of the PV activities, would you consider training the back-up of the national contact person (if the National contact person is unavailable)?

VCLS Answer: It is not a requirement to have a back-up for the National contact person for pharmacovigilance but it's a good idea to have one so they should be trained.