Does Remote Pharma GMP Auditing have a Future?

The two years since COVID struck have seen virtual auditing checks and inspections take the place of on-site visits. Some auditors believe that the tools and adapted services they have developed during the pandemic might offer a permanent solution, but deeper analysis shows that clients have misgivings about this scenario.

Two years on from the first wave of COVID, and following a new survey that was conducted in February 2022, Alasdair Leckie, Operations Director at Rephine, takes a look at clients' auditing preferences.

Before the onset of COVID-19, neither pharma regulators nor suppliers would ever have countenanced the idea of remote audits to verify the manufacturing and distribution standards of supply-chain partners.

But fast-forward and two years of lockdowns, social distancing and travel restrictions have disrupted the former status quo. Regulators such as the European Medicines Agency (EMA) adapted their requirements to ensure that inspections could still take place, rather than having to be curtailed. As well as allowing a grace period, so that marketing authorisation holders did not fall foul of compliance requirements if they failed to maintain a maximum three-year auditing cycle (in Europe), the authorities made provision for virtual assessments to be conducted online.

But remote auditing was only ever intended to be a temporary measure and although they offer appealing convenience for pharma brands and industry regulators alike, the prospect of standardising on remote audits in the longer term appears to be untenable.

Remote inspections simply cannot go into sufficient detail compared to on-site audits, meaning there is a risk that something important might be overlooked. That could be something as seemingly innocuous as a cracked floor – which could present a hazard, breaching compliance. In a live remote session with a video link, these transgressions could be missed if cameras are not directed into every corner.

The View from the Coal Face

In February 2022 Rephine conducted international research among pharma clients and senior auditors to get a better view of how the pharma industry has adapted its auditing activities and to gauge companies' priorities for a post-pandemic future. Of the 30 or so people we polled, just over half were in the quality function of pharma companies, with the balance comprising professional auditors, and around two-thirds of responses were from Europe, the remainder primarily from Asia – particularly India.

For both respondent groups (clients and auditors), the greatest challenge with remote auditing has proved to be the lack of a site tour, which leaves auditees in control of what is shown. This gives much less scope for auditors to spontaneously go off plan and explore behind closed doors.

As a consequence, auditors cited the restricted scope for real-life face-to-face interaction, and the ability to apply their softer skills (eg that sixth sense that something warrants further investigation) as major challenges with remote audits.

Clients agreed that this limitation presented a concern, but worried more about technology-based issues such as a loss of connection potentially preventing or interrupting remote inspections.

Lack of Trust in Remote Audits

Our survey clearly reveals that pharma clients do not trust remote auditing as a permanent solution, with two-thirds saying they would not accept a remote-only audit in order to qualify a new API supplier. Auditors responded in a similar fashion.

By the same logic, almost two-thirds of client company QA respondents said they would not be comfortable going more than two years before re-auditing, following a remote inspection: a fifth said they would want to redo the audit within a year. (Two-thirds of auditors said they would look to re-audit within a year following a remote-only inspection.)

For services like packaging (particularly secondary packaging), remote audits felt more tolerable for pharma clients, but for suppliers of active ingredients or finished products, indefinite reliance on virtual inspections was unthinkable. The vast majority agreed or strongly agreed that remote/virtual audits were a good temporary solution during the pandemic, but a sizeable proportion of client QA respondents felt that remote auditing could even require additional resources, compared with an in-person inspection.

Might Hybrid Solutions be Acceptable?

A hybrid approach to supplier auditing, however, meets with more approval, with two-thirds of audit clients happy with concept. Under such an approach, routine aspects such as sharing and completing documentation could be done remotely but on-site inspections would still take place physically. A third said they would favour a return to 100 per cent in-person audits. Only 1 client expressed a preference for persisting with remote audits across both the documentation element and physical inspections.

Open responses in the survey suggested that the long-term value of remote auditing would be for occasional use only and in the context of a long-term, trusted relationship, and where standard operating procedures had been shared ahead of time. For auditors, it was felt that any decisions about continued use of remote audits would need to be risk based and would depend heavily on the willingness of auditees to cooperate, for instance in making the right documents and people available to maximise results.

Where client respondents had themselves played host to remote audits during the pandemic, three-quarters favoured a hybrid approach in future, whereby a day on site could be combined with a day providing documentation remotely.

In Favour of Third Parties

The idea of working with an independent

third-party auditor to generate a single, comprehensive report that could be shared with multiple customers, rather than allowing multiple auditors on site over 1-3 years met with the approval of almost all respondents.

It was through conducting this kind of activity, with strict observance of social distancing, testing and PPE use, that our own auditors were able to continue conducting on-site audits throughout the pandemic. Although numbers of physical audits halved during 2020 in favour of increased remote activity (and the sharpest reduction in activity was really only during that first global lockdown from March-May of 2020), by 2021 highly accredited auditors located on the ground in target markets were largely back on site – with 82 per cent of inspections conducted in person and just 11 per cent done virtually (compared to a ratio of 72 per cent on-site/28 per cent remote audits in 2020).

Ultimately, however, whatever the perceived convenience of at-distance documentation sharing and virtual inspections, there is no substitute for the real thing and remote activity should only ever be seen as a support activity to the main event.

We do not know what the next phase of the pandemic will bring. Where there are high rates of vaccination and reduced hospitalisations, regions are already seeing a tentative return to some form of normality. In other countries with dense populations and still-high infection rates, the situation over the coming months is more uncertain. The key to maintaining high standards of supplier compliance will depend on continued, tailored vigilance, with a return on-site re-audits as soon as is practicable.

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