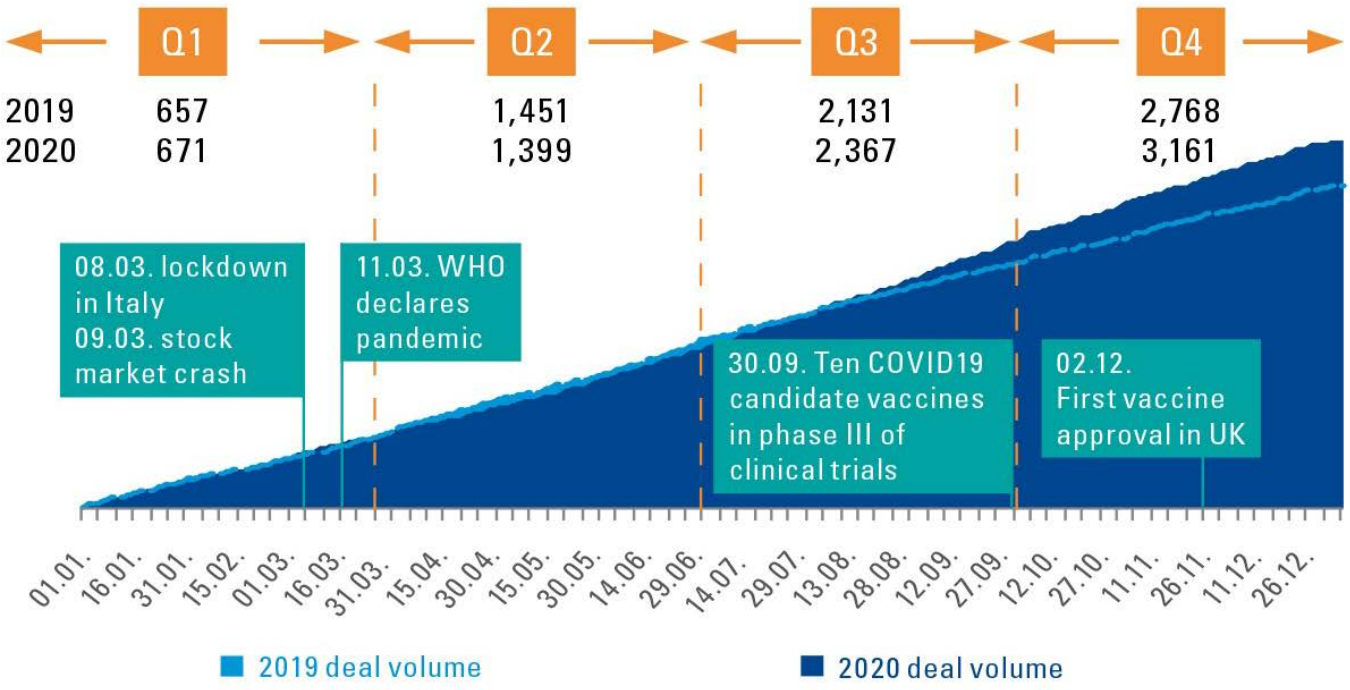
KPMG

Life Sciences M&A in the Asia-Pacific

The Strategic Role of Quality & Compliance

The Life Sciences industry continues to be one of the most buoyant in terms of inorganic growth activity. Driven by the rising costs of innovation development and compounded by growing pricing pressures, Life Sciences companies are increasingly forced to look left and right, sometimes directly at competitors, for strategic partnerships that deliver on the expansion ambitions. According to KPMG's regular Deal Capsule analysis for this industry, the number of transactions announced in 2020 was up 14% on the prior year, which was also gangbusters. Valuations are skyrocketing, ranging from 13 times to as much as 27 times EDIBTA. And this is all happening in the face of the COVID-19 pandemic.

Cumulative Deal Volume amidst COVID-19



Sources: Thomson One; WHO; KPMG, Germany, Analysis

At the same time, Life Sciences, one of the most highly regulated industries, also continues to suffer from brand and ethical reputational challenges in the mainstream healthcare ecosystem. The US Department of Health & Human Services – Health Care Fraud & Abuse Control (HCFAC), which exercises its authority globally, has observed a quadrupling of both the number of defendants as well as number of territories for which charges were brought. The programme, on an operating budget of $1 billion (an increase of $400 million since 2013), saw more than 1,500 investigations resulting in $2.4 billion in judgments and settlements. And the implications go beyond just the financial.

So the question then becomes – is there enough thinking on the connectivity of these two business imperatives (growth and ethics)? Our view is "likely, no" and this article therefore outlines a case study of KPMG's experience in driving Quality & Compliance programme activities to deliver, rather than hinder, a portfolio modification strategy.

Collaborative build of a customer-centric view for the newco

KPMG was asked to support a large Life Sciences company with developing the "to-be" Quality & Compliance organisation in the Asia-Pacific region, following the recent integration of a sizeable portfolio acquisition. The project entailed drafting of the policies and procedures documentation as well as the quality agreement for the combined entity, and building out the responsibility matrix.

Of primary focus was to ensure a smooth handover from the healthcare end-customer's perspective, so as to avoid any disruption in supply. And this is where the story begins – a review of the Order Management processes in view of the transformation and harmonisation of the ERP backbone. Multiple workshops were conducted with the leadership teams of both the parent and acquired entities, the objectives being to:

- Map the "as-is" processes of the entities;
- Build the "to-be" processes for the newco;
- Identify the compliance and controls risks therein; and
- Derive a plan for closing the gaps, including the roles and responsibilities required.

Within the Order Management umbrella as-is/to-be process, the sub-areas of focus typically will include:

Licensing & Registration	Regulatory Affairs should provide the appropriate inputs here so as to ensure "right products, right markets" based on approvals (and any configurations that may be required). Ideally, the information is maintained in a Product Lifecycle Management (PLM) system, which then feeds automated controls in the ERP to guide the Commercial team's behaviours.
Customer Management	Even though customers don't always require approvals, accurate information is key for inventory management, as well as for recalls or serious events. The process should also cover customer training for intended use and feedback loops, as per ISO standard 13485:2016 (more specific to medical devices).
Distribution Management	Beyond tracking inventory, the process must accommodate the needs of Quality Assurance to conduct supplier audits. In addition, and with growing policy pressures such as the European Union's new Medical Device Regulation (MDR), companies must have distribution visibility by product and by market to ensure compliance with policy requirements and timelines.
Field Services	This process is becoming increasingly important in the age of IoT-enabled tools and product + service propositions. Service and maintenance records should be up-to-date to drive product calibration activities. There must also be accurate training records for field teams, ideally in a digital format, for reconciliation in the case of customer complaints or serious events.
Post-Market Surveillance	The importance of timeliness of reporting serious events in this industry cannot be overstated, and regulatory requirements appear to be continuing to travel in the direction of even shorter windows. As product approvals are expedited to provide populations with access to the latest medical innovations, PMS becomes a key tool for not only managing adverse events and recalls, but also in gathering data to enable the telling of the value story that product technologies are delivering to market.

The ultimate objective of the above exercise is to ensure that the newco moves forward in such as way as to achieve the envisioned growth synergies, while also aligning Commercial and Quality & Compliance operations. With the to-be Order Management process in place, allowing for a customer-centric view of the business, Quality Assurance, Ethics & Compliance, and Regulatory Affairs teams can be enablers from the beginning.

De-risk the value streams, and embed with top-notch Quality & Compliance documentation

With a more consolidated view of customer processes in-hand, Life Sciences companies can march ahead to deliver the anticipated benefits of consolidating entities. Beyond Order Management, we propose the facilitation of broader "value mapping" exercises across the key processes, not only for the "to-be" archetyping but also to identify potential risks early on. Working sessions, with Asia-Pacific multidisciplinary teams and inputs from Global, are required in order to align stakeholders. In other words, a real change management programme.

Now it's time to seal these efforts by formalising the newco Quality & Compliance function. In part, this means drafting the policies & procedures documentation and quality agreement, and building out the responsibility matrix. Often the parent company will provide their existing templates to be implemented as an interim north star. Concurrently, the newco can review the templates with the acquired entity's leadership team for applicability, any tailoring required, and buy-in along the way. The documentation should be clear about the functions and people too, with particular clarity between the parent and acquiree company teams. In arriving at the final models and files that are accepted by all parties, it's good to identify remaining open risks that need to be addressed.

The newco is recommended to follow closely the ISO standards here, which detail the requirements for Life Sciences companies to have a Quality Management System (QMS) spanning the product lifecycles across design & development, production, storage, distribution, installation, servicing, and disposal, among other activities. Based on our experience, considerations to monitor for the success of QMS implementation include:

- The rapidly-changing environment in which the newco operates;
- The newco's own evolving and varying needs;
- The objectives and corporate strategy of the newco;
- Product and proposition offerings;
- Key processes across the front, middle, and back offices;
- The newco's size and organisational structure; and
- As the spirit of this article suggests, tuning-in to applicable regulatory requirements.

Taking the concepts forward

We hope this article sheds light on the strategic role of the Quality & Compliance function in the Life Sciences industry, and how a focused plan in this space is mission-critical during portfolio transformation programmes. Whether it be acquisition, divestiture, or some other partnership arrangement, the Life Sciences industry is highly regulated; companies in the Asia-Pacific must keep in sight doing the right things the right way as a guiding principle. History teaches us that, over time, there is a high correlation between ethical and business success.

To take the concepts from the article forward, we provide three options to consider:

1. For those Life Sciences companies with legacy portfolio transformations, yet still suffering from the aftershock, consider a Quality & Compliance "health check" to ensure all bases are covered.
2. For those Life Sciences companies in the midst of a portfolio transformation, seek to avoid the mistakes that others have made previously; use the learnings from previous transformations to your advantage.
3. For those Life Sciences companies in neither of the above situations, it is likely only a matter of time, given the buoyancy of the industry. Start early to anticipate the journey ahead and get stakeholders onboard.

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