Taking Affiliate Quality into the future

How quality organisations must evolve to be future-ready

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Taking Affiliate Quality (AQ) into the future

1. Foreword

The evolution of health markets is being driven by multiple factors. These include digitisation, new technologies and innovative medicines. In addition, personalisation and evolving regulations are forcing life sciences businesses to adjust in order to maximise customer value and maintain their market competitiveness.

Affiliate Quality (AQ) organisations are instrumental in providing oversight on product quality and safety in the markets. To achieve these goals, AQ partners with commercial organisations, and are also experiencing the same pressures to adjust and remain fit for purpose.

This whitepaper, which is based on a benchmarking survey across 10 of the globally-leading 20 biopharmaceutical organisations, outlines the main challenges for AQ and how AQ is responding to master them.

2. Future quality: why AQ needs to evolve

The role of AQ is instrumental in ensuring that high quality biopharmaceutical medicines reach healthcare professionals, hospitals, and patients in markets, as and when needed. For example, AQ assumes responsibility for market import testing, distribution controls, complaint management and, when needed, product recall execution.

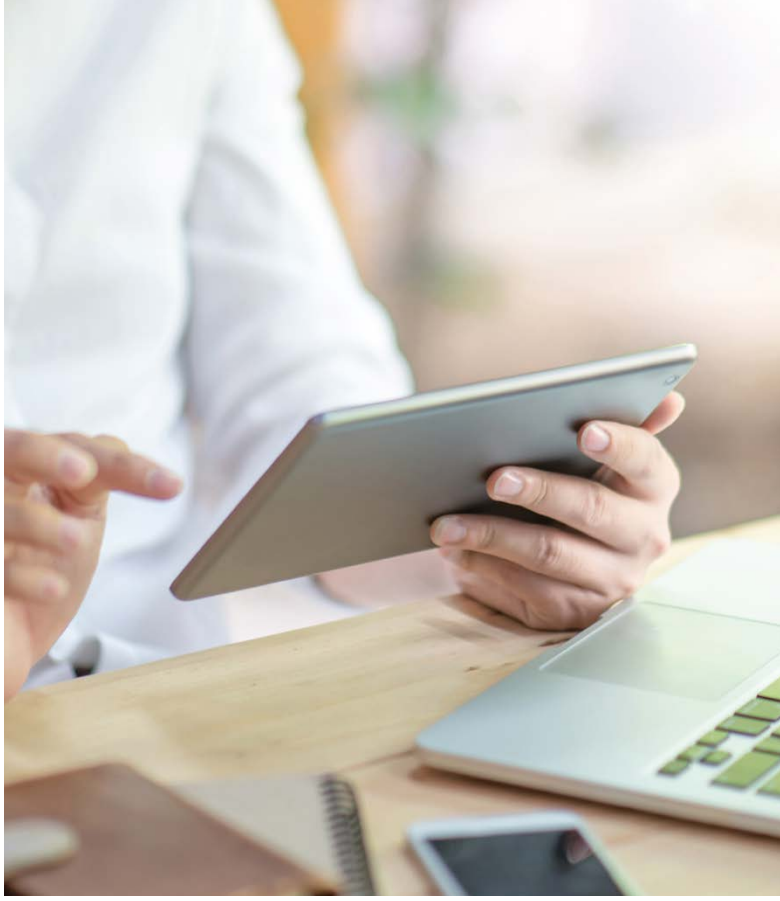
As health markets and the pharmaceutical landscape continue to evolve, there is a constant need for AQ to adjust and adapt in order to remain fit for purpose. To do that, AQ needs to master the following key challenges:

- Evolving local regulations and increased scrutiny by inspection authorities require AQ to constantly prepare for upcoming and changing regulations, and effectively demonstrate a state of control to meet regulatory expectations. Examples of evolving regulations include the role of the Market Authorisation Holder in the EU or the GMP certificate in Russia.
- Biopharmaceutical companies tend to significantly increase the number and variety of their medicines, which expands the scope and complexity of requirements that AQ need to be prepared for and address. This includes establishing new capabilities to effectively support digital medicines or getting ready for home delivery of products and telemedicine.
- Biopharmaceutical companies need to overcome and reduce the internal complexity of their GxP[1] regulated IT system landscape, which often comprise a broad spectrum of systems. These lack interconnectivity, which results in a fragmented picture and disrupted workflows, making it hard for AQ to fully benefit from digital solutions, including analytics.
- To fulfil their advanced and more complex role, AQ need to infuse a mindset of business partnering in their organisation. This will enable them to anticipate the needs of their business stakeholders and proactively propose solutions to them. Partnering effectively is critical to establishing the greater flexibility and speed needed to address the growing variety of regulatory and business expectations facing AQ.
- As a result of the increasingly demanding work environment described above, AQ is struggling with a higher workload and needs to overcome the challenge of keeping AQ resources highly motivated and engaged, especially in affiliates with limited resource capacity.

[1] GxP is the abbreviation of "Good x Practice quality guidelines and regulations". The "x" in GxP stands for the field the guidelines and regulations apply to in the pharmaceutical industry: **GCP** = Good Clinical Practice, **GDP** = Good Distribution Practice, **GLP** = Good Laboratory Practice, **GMP** = Good Manufacturing Practice, **GVP** = Good Pharmacovigilance Practice

To explore these issues in depth, PwC carried out an AQ benchmarking exercise across 10 of the world's 20 leading biopharmaceutical organisations.[2] We set out to explore the nature of these pressing challenges, AQ organisations' responses, and how they aim to become fit for the future.

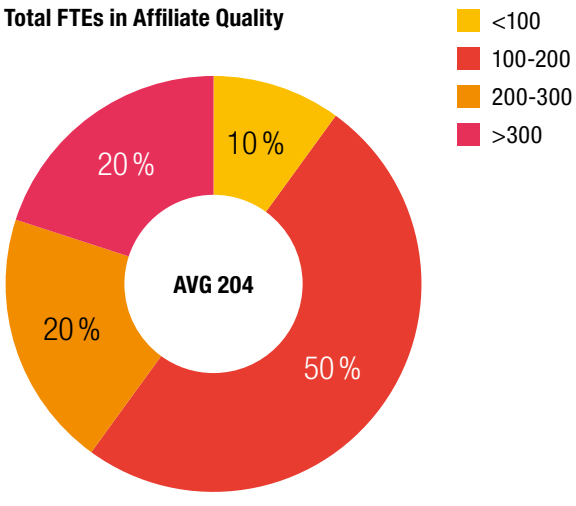
This whitepaper highlights the situation and perspectives of the participating companies along the dimensions of PwC's Quality 4.0 Framework (see next section for details). Our aim is to provide food for thought and inspiration for biopharmaceuticals exploring how they can improve their own AQ operations.



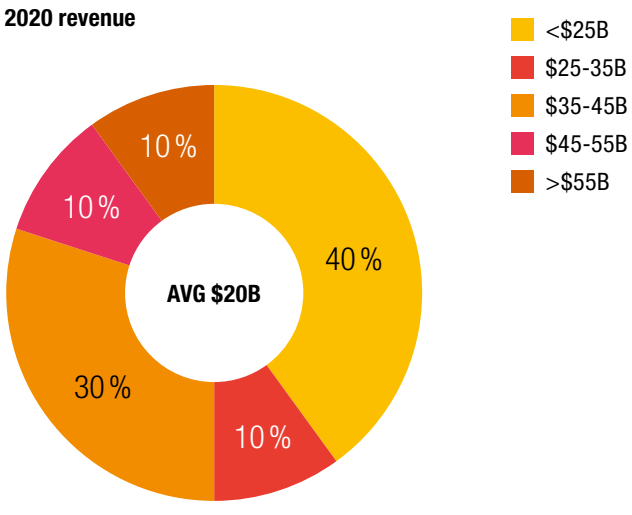
Benchmark profile:

- **10 of top 20 biopharmaceuticals**
- **60+ meetings with AQ leaders to understand the characteristics, challenges, and strategic goals of each AQ organisation**
- **standardised survey completed by 400+ AQ personnel and AQ business stakeholders[3]**

Graph 1: Size of the benchmarked AQ organisations in FTE



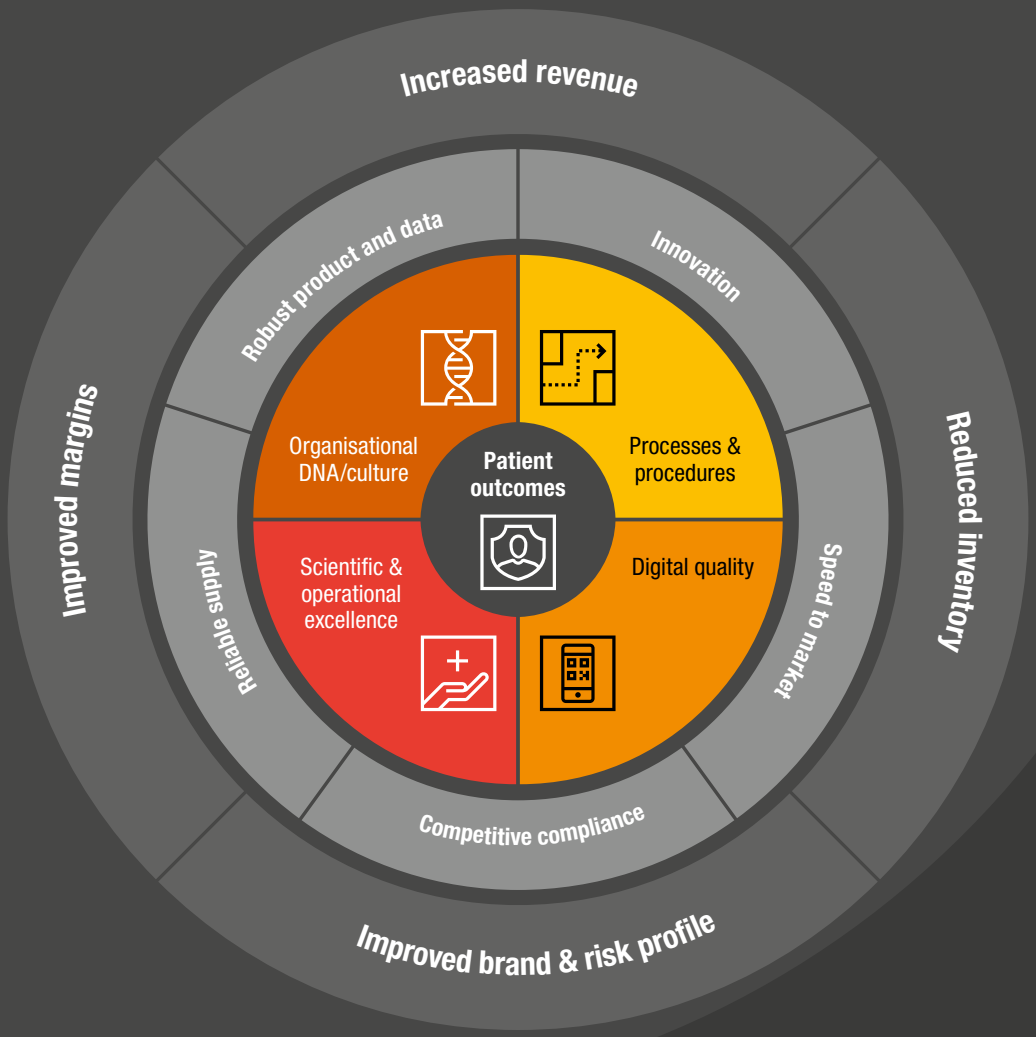
Graph 2: 2020 revenue of the benchmarked companies in $B



[2] Top 10 out of top 20 global pharma organisations based on 2020 revenues.
[3] Approx. 80 % of all survey participants were AQ personnel and approx. 20 % business stakeholders.

3. How PwC's Quality 4.0 Framework can guide the journey ahead

Graph 3: PwC's Quality 4.0 Framework



PwC has developed a Quality 4.0 Framework that aims to guide quality organisations on their journey to becoming product- and patient-centric and deliver tangible benefits to patients, regulators and the business, while effectively and efficiently maintaining compliance.

The framework consists of three concentric circles, all built around improving patient outcomes, which is the ultimate goal of quality and the central point of the PwC Framework.

- **The outer circle** highlights the business outcomes that are fundamental for business continuity and growth.
- **The middle circle** emphasises operational outcomes: the goals that the AQ organisation contributes to attaining either directly or indirectly.
- **The inner circle** focuses on the four key dimensions around which every organisation, including quality, is organised.

Together, the three circles cover all topics that need to be prioritised and aligned to ensure the quality organisation's success.

Our benchmark mainly focuses on the organisational DNA/culture dimension of PwC's Quality 4.0, but also touches on processes & procedure and digital quality.

4. Challenges and opportunities

a) How does AQ add value?

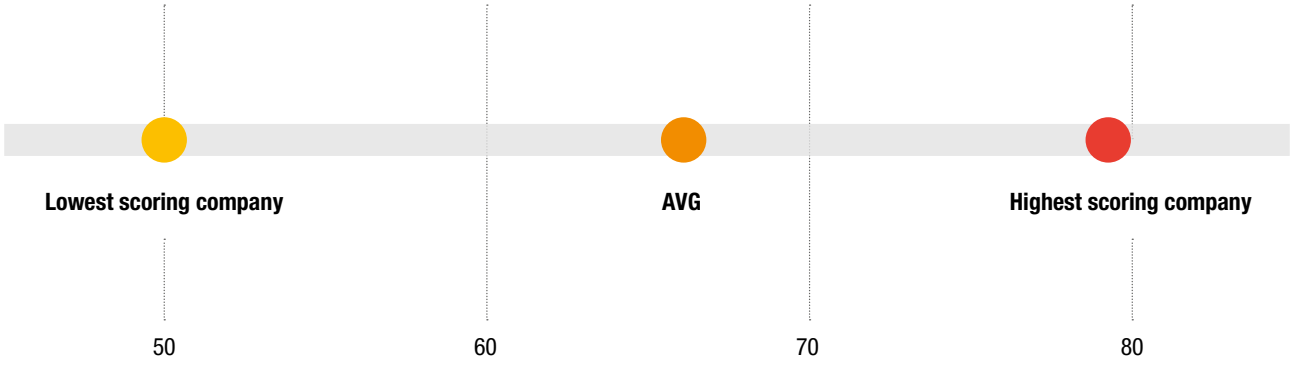
AQ makes a strong value contribution to the overall success of biopharmaceuticals. It does this by providing oversight and control of the distribution of medicines in markets, safeguarding a reliable supply of high quality products to patients, and ensuring product surveillance.

Ensuring a reliable supply, dealing rapidly with patient inquiries and complaints, and professionally collaborating with authorities are all fundamental for securing the licence to operate and protecting biopharmaceuticals' reputations. All this either directly or indirectly contributes to reducing inventory, enhancing the company brand, and lowering its risk profile, securing, and increasing, revenue and strengthening profit margins.

Our benchmark survey supports the major strategic relevance and strong value contribution of AQ in biopharmaceuticals.

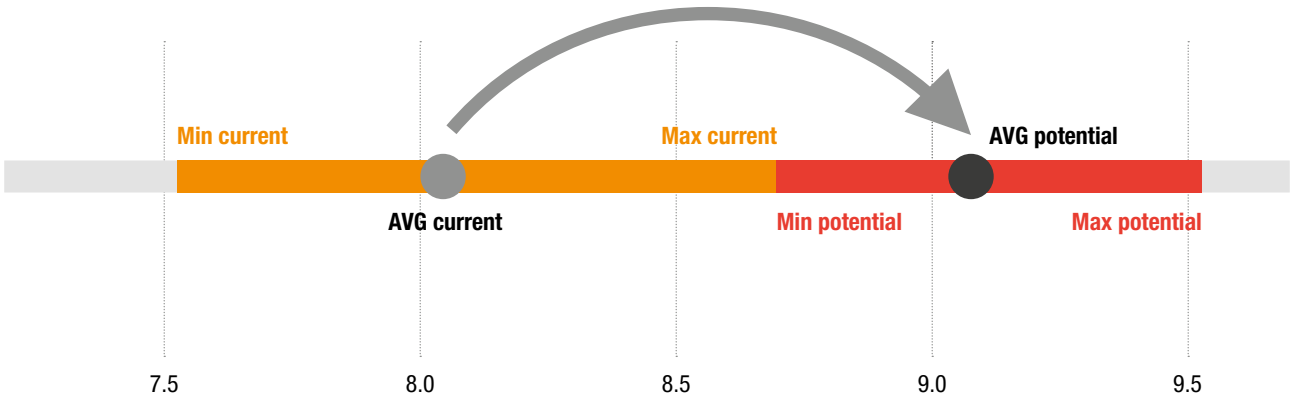
67 % of all participants consider AQ as a competitive advantage, with some companies scoring close to 80 %.

Graph 4: Perception of AQ as a competitive advantage in % of survey participants



The current value contribution of AQ is rated high across all biopharmaceuticals by both AQ personnel and their business stakeholders.

Graph 5: AQ's current and potential overall value contribution on a scale of 1 (minimum) – 10 (maximum)



Min current/potential = lowest scoring company
Max current/potential = highest scoring company

Survey participants consider the following areas as AQ's most relevant value contributions:

a. **assuring product quality and patient safety**

b. **adhering to internal and external requirements**

c. **efficient monitoring and removal of defective products.**

While this result is not unexpected, some biopharmaceuticals go beyond the more traditional role of AQ. Best in class practice is to leverage AQ's strong analytical, methodological and management capabilities to drive more general simplifications and improvements across affiliates. As a side effect, this helps make AQ resources' jobs more attractive and rewarding.

Table 1: Value provided by AQ (mentioned by survey participants in %)

Provided value	Lowest scoring company	AVG	Highest scoring company
Assuring product quality & patient safety	10.9	12.1	13.2
Adherence to internal & external requirements	10.3	11.6	12.2
Efficient monitoring and removal of defect products	9.6	11.4	12.1
Support GxP relevant projects	10.3	11.3	12.2
Efficient regulatory compliance risk management	9.6	10.6	12.0
Systemic reviews of the Quality Management System (QMS) performance	9.4	10.6	11.4
Educating distribution partners on GxP	8.3	9.8	10.7
Fostering continuous learning	5.8	7.7	8.8
Securing highest level of trust to brands	6.8	7.5	8.8
Support process efficacy (cost & speed)	4.9	6.5	8.5

b) How to address internal challenges and realise AQ's strategic goals

While AQ adds value to both the organisation and patients, it also faces some internal challenges. Benchmark survey participants across all biopharmaceuticals ranked the following as the most pressing for AQ:

a. **AQ resources are constrained/limited**

b. **AQ is not informed in a timely manner nor engaged early**

c. **Execution of quality processes and tasks is too slow**

d. **Decision-making takes too long or is ineffective**

Table 2: AQ's common challenges (mentioned by survey participants in %)

Challenges	Lowest scoring company	AVG	Highest scoring company
AQ resources are constrained/limited	23.8	30.1	42.1
AQ is not informed timely and early engaged	7.3	17.4	21.9
Too slow executing of quality processes and task	7.5	12.8	17.4
Decision-making takes too long or is ineffective	5.1	10.3	15.8
Unclear or unspecific quality strategy	5.7	9.4	12.5
Misaligned or delayed quality related communication	2.3	5	12.5
Goals/objectives are misaligned	0	4.3	7.9

To address these challenges and get fit for the future, AQ leadership across all biopharmaceuticals aims to achieve the following common strategic goals:

1. **Increasing the capabilities of AQ personnel with a strong focus on "strengthening business partnering"**
   Making sure that AQ personnel have a stronger business partnering mindset and greater business acumen is expected to serve as a catalyst to better address AQ's most pressing challenges (mentioned above) and most effectively achieve AQ's strategic goals. Requirements of a good AQ colleague are "being a strong 'matrix' contributor" and "plant experience is preferred in order to know who to contact."

2. **Increasing AQ's value contribution to the business, customers and patients**

3. **Fostering a proactive risk management culture**

4. **Simplifying/optimising quality operations and processes**
   An increased focus on "operational excellence" is expected to streamline and simplify quality processes to free up resources and enable AQ personnel to focus on higher-value activities such as business partnering.

5. **Optimising the footprint of quality workforce**
   Increasing the AQ workforce's agility is expected to help address resource constraints/limitations and enable them to respond faster to affiliates' fluctuating needs.

6. **Ensuring GxP compliance and the licence to operate.**

"We have one simple QMS with 23 elements that can apply in each affiliate. This sets clear expectations for our affiliates on policies, standard operating procedures, templates on what is mandatory. We prioritise governance and quality councils, artwork controls, distribution and product storage, deviation management, corrective and preventive actions, and risk management.[4]"

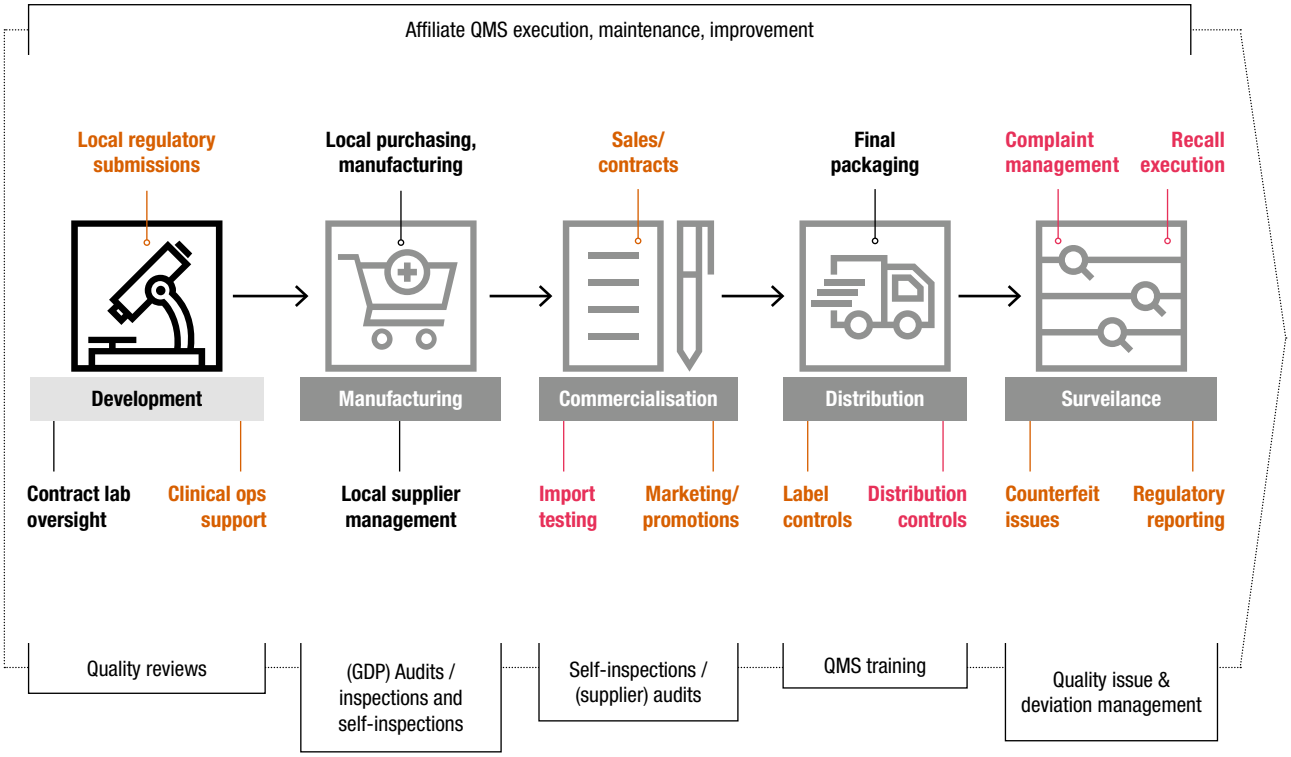
[4] The quotes mentioned in this paper are from different anonymous industry leaders and experts.

c) AQ responsibilities and size of AQ workforce

Graph 6: Typical responsibilities of AQ

Laboratory to patient

Primary responsibility: Ensure product quality once released for distribution
Local responsibilities: Support in-country quality requirements
Integrate with other functions: Regulatory Affairs, Pharmacovigilance, Supply Chain, Clinical, etc.



While AQ responsibilities are widely comparable across peers, there are some differences, including:

- **Development:** while some biopharmaceuticals include development activities within their scope of responsibilities (such as contract lab oversight or supporting other functions with local regulatory submissions and clinical operations) some only do so partially, others exclude it entirely.
- **Distribution:** label controls may or may not fall within the AQ organisation's scope of work.
- **Transport:** some biopharmaceuticals take responsibility for global transportation, while others assume responsibilities only when the product enters the affiliate/market.

The scope of the affiliate QMS for which AQ is responsible varies. At the very least it covers GDP responsibilities with a few GMP aspects (e.g. local-repackaging, relabelling, overseeing related third parties), while in the most extended version we saw, AQ covers all GxP responsibilities (GDP, GMP, GCP, GVP). It should be noted that since PwC's Affiliate Quality Management Survey 2017[5], there has been a trend towards having one integrated affiliate QMS that is harmonised across the biopharmaceutical company.

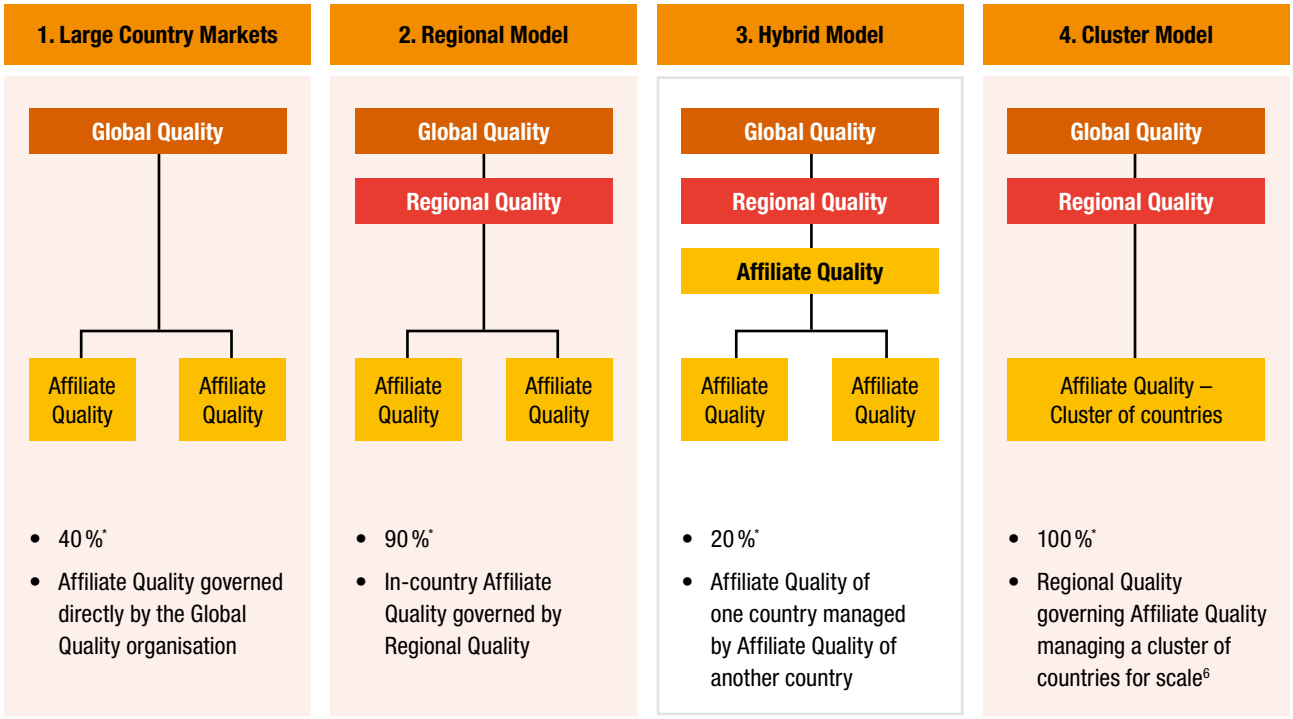
While the scope of responsibilities assumed by AQ correlates with the size of the AQ organisation and workforce, making a meaningful comparison of the relative scale of AQ across biopharmaceuticals would require a wide range of additional considerations to be taken into account. These include affiliate structure; distribution network and channels; number and variety of products (product portfolio); specific applicable local regulatory requirements and organisational design principles relating to geographic proximity and physical presence in the local market. This was beyond the scope of this benchmarking survey.

[5] PwC survey conducted as part of PwC's facilitated Quality Roundtable, unpublished.

d) What are the leading models for AQ governance?

During our benchmarking research, we noted four main governance models (as shown in graph 7). Each biopharma organisation tends to apply a combination of two to three of these, according to geographic/market specificities. Regional and Cluster models are mostly widely used across all 10 participating biopharmaceuticals, with 40 % of the biopharmaceuticals also applying the Large Country Markets model. Based on the overall benchmark observations, we can conclude that all governance models have the potential to be applied successfully and result in an AQ organisation that performs well.

Graph 7: The four observed governance models



* The percentage indicates how many of the observed organisations apply the governance model.

Primary models observed

> **Not all countries have affiliates. We sell products in about 100 countries, and about 80 have country quality organisations. Some are responsible for more than one country. Local contract manufacturing and re-packaging differentiates the types of countries and AQ scope. There are also cluster quality organisations where country quality reports to the cluster quality head."**

[6] The Cluster model is typically applied in the LATAM, Asia, Africa and/or Middle East regions.

“There is at least one dedicated AQ member in each affiliate. All fall under the AQ budget. We made sure that we got the right level of resource in place and established service agreements with the commercial organisation to be clear on who is doing what. We also set expectations on howour commercial colleagues would provide support and representatives for deploying quality council etc.”

e) The power of AQ hubs

Our benchmark reveals an emerging trend towards uplifting “local” operational AQ activities[7] from within affiliates to regional/global hubs. This aims to drive quality of service, standardisation, and operating efficiency. As a side effect, hubs also serve as a vehicle to allow AQ to reduce or even eliminate their physical presence in small affiliates, if permitted by local regulations, simplifying the management complexity of AQ resources.

Typical activities in scope for uplifting into the hubs are complaints intake and triage for further processing by local AQ; preparation for local product release with the release performed by local AQ; self-inspection management; training administration; supplier qualification and oversight; change control/change request management; deviation management; IT system validation and cold-chain management.

Forty per cent of the participating biopharmaceuticals already operate hubs, mostly regional, and aim to further expand the scope of these hubs. Most of the remaining biopharmaceuticals are considering establishing hubs to uplift activities in the near future.

[7] Excluded are typical activities under the responsibility of global/regional quality such as establishing and maintaining the global QMS/procedures, global quality/key performance indicator (KPI) reporting, fostering best practice sharing across AQ, fostering process harmonisation and simplification.

f) Organising AQ – what are the structures?

Our benchmark investigated the following:

- AQ organisational structure focusing on solid vs. dotted reporting lines and budget control
- Resourcing model and whether the AQ job is executed by full-time dedicated resources or allows for hybrid resources that perform the AQ job part-time and additionally take on some responsibilities of other neighbouring functions such as regulatory and safety.

The benchmark has revealed two structures that can be characterised as follows:

Structure 1:

Solid reporting line into quality with/without dotted line into the affiliates:

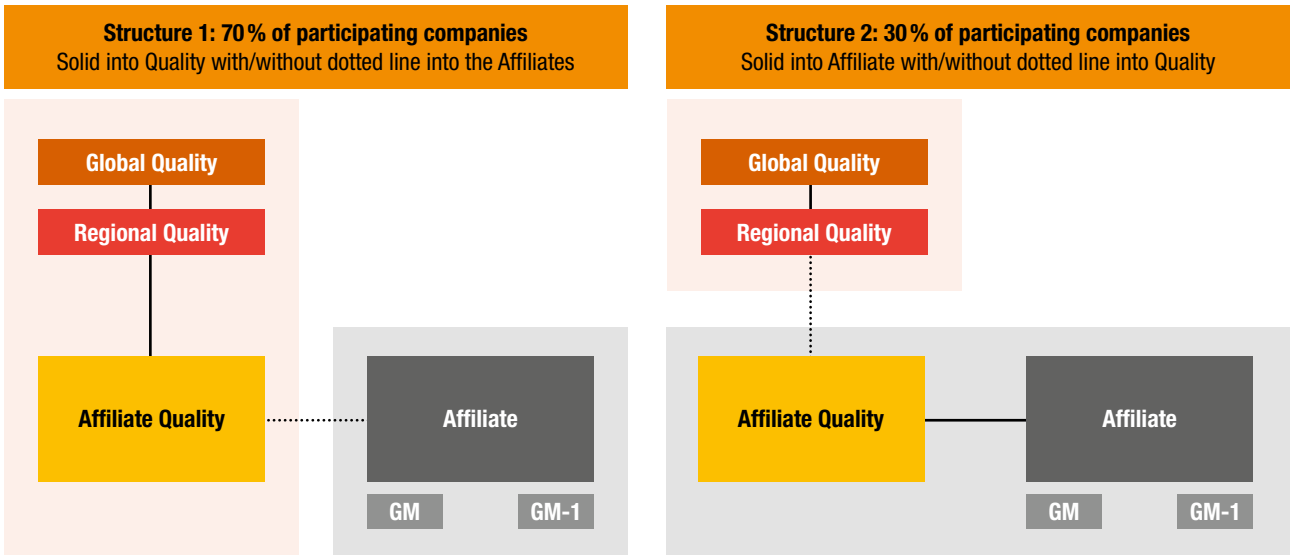
- Global/regional AQ assumes full control of AQ resources in the affiliates
- AQ in the affiliates has either a dotted line into the General Manager (GM) or GM-1 or no reporting line into the affiliate organisation
- Only dedicated AQ resources (jobs)
- The budget for AQ within the affiliate is mainly controlled by global/regional AQ

Structure 2:

Solid reporting line into affiliate with/without dotted line into quality:

- Global/regional AQ providing oversight and support for AQ in the affiliates
- Affiliate Quality has direct line to GM or GM-1
- Either dedicated-only, hybrid-only or a combination of dedicated and hybrid resources
- Budget for AQ within the affiliate is mainly controlled by the affiliate

Graph 8: The two observed organisational structures



Our benchmark reveals that 70 % of participating biopharmaceuticals operate with the “Solid into Quality” structure. And there has been a strong trend over the past few years to move from a “Solid into Affiliate” into a “Solid into Quality” model, associated with the elimination of hybrid resources. In fact, the overall benchmark suggests that Solid into Quality and dedicated resources lead to higher AQ performance.

In general, and across all participating biopharmaceuticals, the overall AQ workforce is comprised of approximately 90 % internal workforce and up to 10 % externals, mostly contractors and only very rarely service providers.

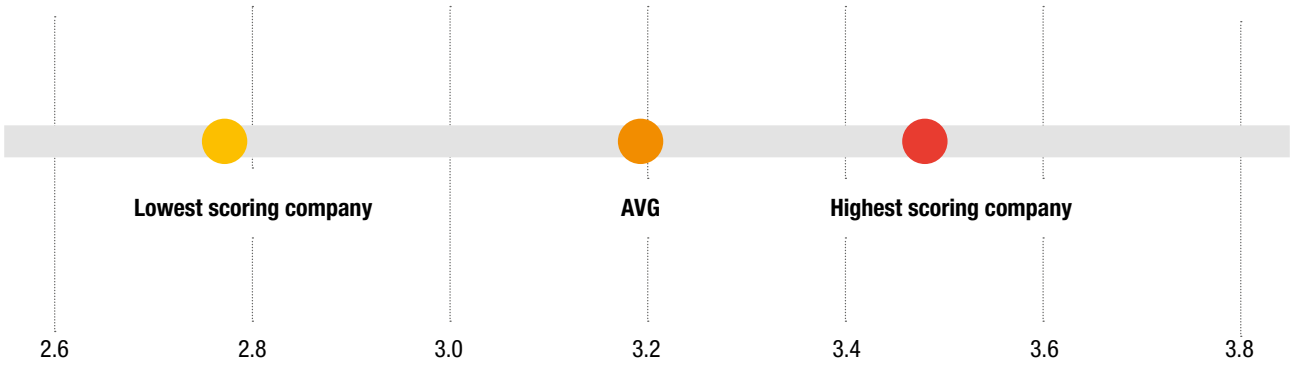
g) How to get talent into AQ

A common challenge reported over the last few years has been finding the right talent from within or outside the company to join AQ, as well as creating an attractive and motivating team spirit and work environment to develop AQ personnel.[8]

- Generally, there is a view that "regulatory" experience and talent is easier to find in the affiliates compared to "quality". Many biopharmaceuticals report that they are net exporters of talent from within their company and need to acquire talent from external sources.
- Creating a motivating team spirit is intrinsically a challenge for AQ owing to the very small size of AQ teams in many affiliates.
- Added to this is the fact that for most participating biopharmaceuticals, AQ jobs attract lower levels of compensation compared with comparable jobs in the affiliates, e.g. in Regulatory or Safety. This hinders the ability to attract talent into AQ, especially from within the company. Lower levels of compensation are explained by "historical" reasons. But these are increasingly perceived as "unfair" given that performing AQ roles successfully has become more and more demanding and the required set of competencies and degree of experience required to deliver effectively have increased.

We investigated the current level of job attractiveness of AQ positions compared to other available positions in the affiliates (Graph 9). Surprisingly, our benchmark reveals that for 80 % of the participating biopharmaceuticals, the AQ job is considered slightly more attractive than other jobs in the affiliates.

Graph 9: AQ's job attractiveness compared to other jobs on a scale of 1 (minimum) – 5 (maximum) with 3 indicating comparable job attractiveness



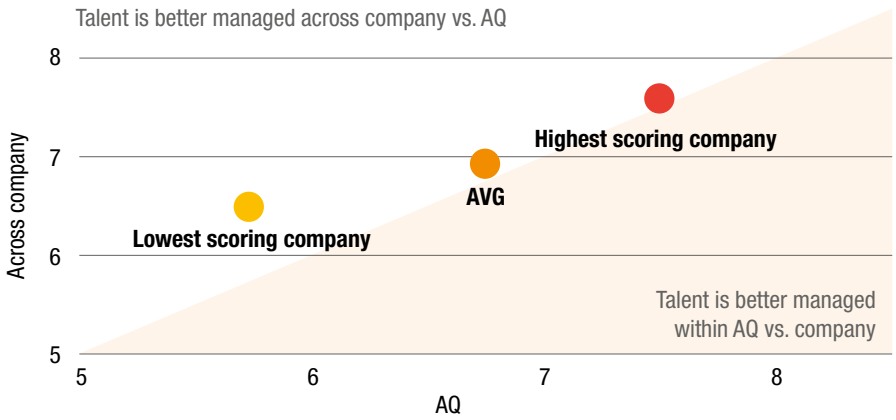
Stakeholder interviews suggested that this may be because, compared to the rest of the company, AQ organisations have become better at taking care of their people and managing their talent.

"By design, the General Managers of our regions and affiliates have no influence on our AQ personnel performance and pay. We do not mix the AQ job and other functions. In some affiliates, we would need less than a full headcount, but we will not combine roles. To maintain independence, we solve this by splitting e.g. 3 AQ people to cover 7 countries."

[8] Also reported in PwC's Affiliate Quality Management Survey 2017.

However, and when zooming into the performance of talent management in the whole company against the AQ organisation, our benchmark reveals that company talent is generally managed as effectively or even more effectively than AQ talent with a potential for general improvement (Graph 10). In fact, only one biopharmaceutical reported that AQ talent is managed slightly more effectively than talent in the rest of the company.

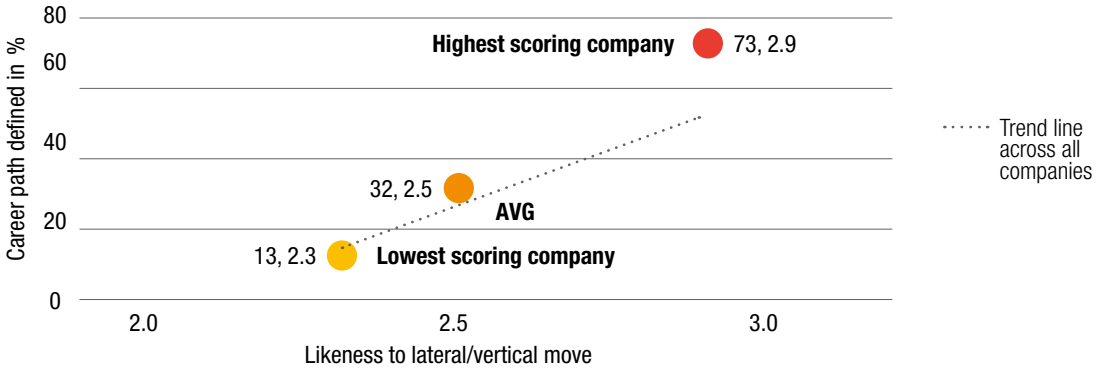
Graph 10: Effectiveness of talent management within AQ and across company on a scale of 1 (minimum) – 10 (maximum)



A generally proven measure to increase job attractiveness is providing opportunities for vertical and lateral career moves. And a clearly defined career path for job holders is expected to increase the likelihood of making such moves successfully. We investigated the availability of clearly defined career paths for AQ and the likelihood of either vertical or lateral career moves by AQ personnel within the participating biopharmaceutical (Graph 11).

While our benchmark confirms a positive correlation between defined career paths and a higher degree of career moves, many biopharmaceuticals do not currently have defined career paths for AQ in place. One reason for this is that AQ teams in the affiliates are relatively small (with very often only one or two staff members) so defining career paths from the "bottom-up" for them is simply not the priority for the affiliates. Neither have many biopharmaceuticals yet attempted to establish "top-down" career paths for AQ company-wide across all affiliates. That being said, some of the biopharmaceuticals reported that maturing career-path management more generally, and for AQ specifically, is high on their agenda to better develop their people and help increase the attractiveness of AQ jobs.

Graph 11: Correlation between a defined career path (in % of survey respondents) and the likeness of a vertical/lateral career move on a scale of 1 (highly unlikely) – 5 (highly likely)

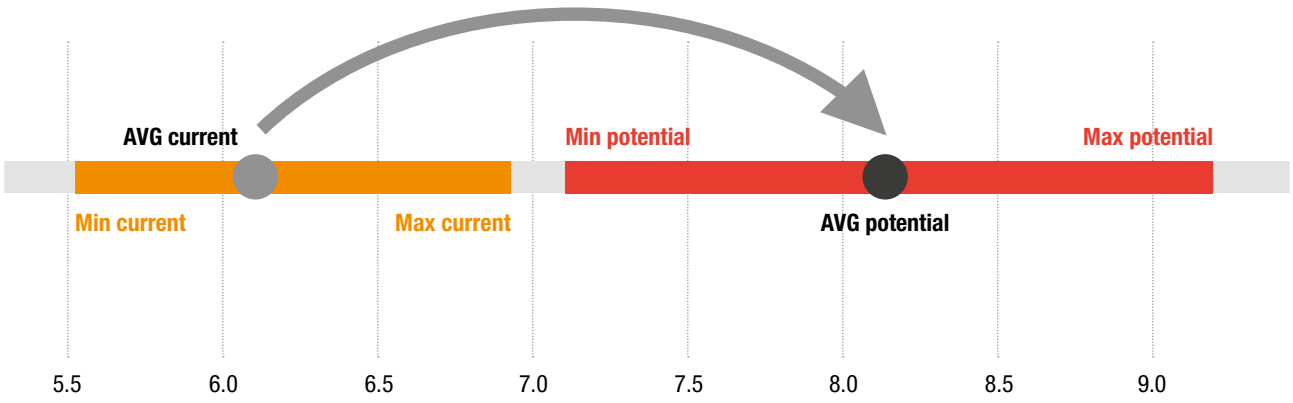


To summarise, increasing the attractiveness of the AQ role and attracting more talent into AQ are clear challenges. Generally improving talent management for AQ resources, fostering lateral and vertical career moves for AQ personnel by establishing career paths for AQ and considering a re-evaluation of AQ job compensation are potential measures that biopharmaceuticals might take to help resolve those challenges.

h) Harnessing the digital advantage

Our benchmark reveals the potential for AQ to benefit from a higher level of digitisation and automation that would create significant operating efficiencies and enable knowledge management globally. Based on benchmark survey respondents, the level of current digitisation and automation ranges between 5.5-7 points on a scale from 1-10, with almost all biopharmaceuticals highlighting a possible improvement of 1-3 points, suggesting that there is significant potential for further gains.

Graph 12: AQ's current and potential digitisation/automation level on a scale of 1 (minimum) – 10 (maximum)



Min current/potential = lowest scoring company
Max current/potential = highest scoring company

Digitising operations company-wide and at scale requires well thought through, multi-year transformation programmes, strong investments, and dedication. AQ depends on such company-wide programmes to effectively benefit from digitisation and automation.

Some biopharmaceuticals reported that they have in the recent past run digital transformation programmes from which AQ benefited, while others are currently running such programmes or plan to initiate them shortly.[9]

"AQ still operates under multiple disparate IT systems across the organisation which is cumbersome and and wastes our AQ colleagues' time."

[9] Interested in learning more from the leading companies in digital transformation and how you score relative to them? PwC's survey highlights the common characteristics of the top 5 % of companies that consistently invest in digital transformation and the benefits those leverage. You can find more on PwC's survey here: https://www.pwc.com/us/en/library/digital-iq.html

5. Conclusion

Our research and experience working with AQ organisations reveals that all participating biopharmaceuticals recognise both the need to evolve their AQ operations, and the benefits from doing so. The best in class biopharmaceuticals have a more acute understanding of AQ as a competitive advantage and, as a result, have invested greater time and effort in the past to improve it.

AQ needs to become fit for the future. Our benchmarking research highlights a number of measures to make this happen. These include:

- Strongly focusing on making the AQ job more attractive.
- Increasing business partnering capabilities of AQ resources to help them play a more strategic role in the affiliates.
- Making the AQ job a full-time role.
- Steering the AQ organisation and resources more "centrally" combined with leveraging AQ "hubs" to drive quality of service, standardisation, and operating efficiency.

The best in class biopharmaceuticals are applying these measures and enhance the effectiveness of their AQ and grow the value it generates.

"The affiliate is typically the marketing authorisation holder. AQ must take responsibility for the release of product in country, the maintenance of quality agreements with manufacturers, oversight on local service providers for storage and logistic activities, complaint handling in country, recall handling, change control, deviation management, audit and inspection performance etc. Quality management reviews are held twice a year to look in-depth into data and quality performance. AQ is purely on the commercial side and has a clean separation from manufacturing quality."

Contacts

Our team is here for you and will be happy to answer your questions or discuss topics that interest you.

Bodo Baumeister
Partner
PwC Switzerland

+41 79 831 48 90
bodo.baumeister@pwc.ch

linkedin.com/in/bodo-baumeister

Jan Paul Zonnenberg
Partner
PwC US

+1 617 901 2066
jp.zonnenberg@pwc.com

linkedin.com/in/jpzonnenberg

Salil Thakar
Partner
PwC US

+1 616 308 0605
salil.thakar@pwc.com

linkedin.com/in/salilthakar

Philipp Hespe
Director
PwC Switzerland

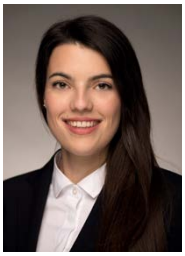
+41 79 592 79 55
philipp.hespe@pwc.ch

linkedin.com/in/philipp-hespe

Theodore Milonas
Manager
PwC Switzerland

+41 76 309 92 57
theodore.milonas@pwc.ch

linkedin.com/in/theodoremilonas



Wiebke Dürichen
Senior Associate
PwC Switzerland

+41 76 329 67 79
wiebke.duerichen@pwc.ch

linkedin.com/in/wiebke-duerichen

For more information: www.pwc.ch/pharma