



Cannabis operational risk Views from quality assurance professionals

QA functions: key to managing operational risks

The year 2020 has brought many challenges for the quality assurance (QA) function¹ at cannabis cultivation and processing sites. In addition to the repercussions of COVID-19, several regulatory changes have shifted the operational landscape. The QA function is instrumental in managing such challenges to an organization's risk, and it cannot be underestimated as we navigate the new normal. To deliver safe, high-quality products to consumers while maximizing value, executive managers and boards need to understand and support the QA function, drawing on the experience of their QA team to establish and maintain a solid risk management program.

To identify, understand, and successfully manage operational risks during this disruptive time, we sought to discover what cannabis QA professionals in Canada are thinking and experiencing. We therefore convened 35 industry professionals from across the country for informal roundtable discussions throughout July and August 2020. These roundtables brought to light numerous important observations and recommendations for industry leaders, which this paper outlines.

1. For the purposes of this paper, QA will refer to both the quality assurance (QA) and regulatory functions at cannabis cultivation and processing sites. Some operations have combined QA and regulatory into one role, while others maintain separate designations. However, under the federal Cannabis Regulations, the responsibility for both QA and regulatory compliance lies with the quality assurance person (QAP).

2020's impact on cannabis QA

The pandemic has significantly affected cannabis operations in many areas, from staffing difficulties and protective equipment shortages to requirements for physical distancing and remote management. The ongoing challenges with access to capital also mean cannabis companies are reprioritizing their investments in compliance and initiatives that directly affect the QA function. At the same time, the industry experienced a number of regulatory changes, including a reduction in regulator oversight for licence amendments and the move from in-person inspections to remote compliance assessments.

The regulatory changes seem small when considered individually, but collectively they have had a substantial impact: more of the responsibility for maintaining compliance is being placed on licence holders. Layering on the consequences of COVID-19 and ongoing investment challenges, it's likely operational risk will remain in flux as the industry continues to mature.

Top four concerns of QA professionals this year

1. Less QA oversight and support

While not all cannabis operators experienced COVID-19 the same way, many QA professionals moved at least partially to overseeing their teams' activities remotely as part of the measures taken to mitigate the risk of COVID-19 transmission. Reducing the physical presence of QA professionals on-site, however, meant that licensed sites have had to increase their reliance on their non-QA personnel to ensure compliance; they responded with cross-training and methods for remote supervision. Those organizations that already had a well-trained workforce were better prepared to react rapidly to the needs of the business, quickly adapting to the changing work environment with revised procedures and continuing operations with a level of trust that the operation was compliant.

Facility operators had to make hard choices about where to direct their resources. Some rescheduled non-urgent (yet mandatory) compliance programs, such as internal audits, to allow the business to focus on more immediate operational concerns. The pandemic also brought delays in routine communications with the regulator, which left questions unanswered and caused even more uncertainty in operational elements. The latter becomes especially important for licence holders navigating the end of the transitional provisions, due to expire in October 2020². Several QAs felt the normal level of support was not available in the summer of the pandemic.

2. Remote regulatory inspections increase risk to industry

With some exceptions, the majority of QA professionals in our roundtables acknowledge the move to remote inspections is not positive for the industry. Initially, there was optimism that remote inspections would improve the efficiency of the process. The actual experience, however, was that inspections took longer to respond to and close, and also required additional labour for scanning and digitizing documentation.

The view among QA professionals is that remote inspections understandably narrow the field of view of the inspectors, who will see only the information presented to them. This narrow view could jeopardize the assessment of the regulatory compliance of the facility. Companies also lose the benefit of real-time feedback and discussion with the inspectors, who would typically confirm interpretations of good production practices.

With the distractions of COVID-19, there is also a fear of complacency. The QA professionals we spoke with expect inspectors will be looking for the risk left behind from temporary changes made to accommodate COVID-19 measures when they return to on-site inspections.

Additionally, it was noted the responsibility for hosting virtual inspections tends to lie only with the QA function—more so than with on-site inspections. This is not by design of the inspectors, but rather the expectation from the cannabis operation that the QA department will handle the inspection. By contrast, on-site inspections tend to involve other functions, which represent their areas of responsibility during a site tour.

Generally speaking, QA professionals look forward to the return of inspectors to their facilities and the legitimacy an on-site inspection brings to the compliance rating. Being inspection-ready at all times is, in itself, a strong mitigation of risk in this area.

3. Changes to the amendment process are positive, but the timing is questionable

Cannabis QA professionals are familiar with the rapid rate of change in rules for licensing and amendments, but the ones we spoke with are split about whether now is the right time to introduce the latest change: one that places more responsibility for compliance onto licensed cannabis sites.

Some acknowledge the industry has increased regulatory reporting requirements in comparison to other regulated markets and think these changes are a step in the right direction, a positive signal of the regulator's trust in the industry. But other QA professionals feel it could be a step too far too early. Some express concern that problems will be found because licence holders were not adequately

2. When the amended Cannabis Regulations came into effect on October 2019, provisions were put into place to help licence holders transition to the new requirements. As of October 16, 2020, these transitional provisions will cease, and all requirements of the Cannabis Regulations must be met.

prepared to operate with reduced oversight, increasing the risk of a compliance decision being reversed later.

4. HR allocation and training is important

Reduced access to capital is the main reason cannabis operators have made shifts in their workforce. Industry-wide layoffs have been common over the past and staffing to handle the complications of COVID-19 amplified the need to reallocate workers. Not all QAs were directly affected—some saw continued growth in their departments, but others experienced direct cuts, increased workloads, and the reallocation of responsibilities to non-QA personnel.

Many of the QA professionals in our roundtables believe there is a need to act as a team, using everyone's skill sets in new ways and ensuring training, cross-training, and teamwork. It was evident from our discussions that companies with a positive and trusting relationship between QA functions and non-QA functions were able to quickly move to this team model, while those organizations that didn't have such good relationships were not as nimble in their reaction times.

A quality-centric culture embraced and supported by the top management and the board is a key mitigation tactic for any cannabis organization.

QA professionals' priorities for the future

The QA professionals we spoke with have a positive outlook for the future of cannabis despite the complex challenges 2020 has introduced. To achieve future success, they contend management and boards must focus on action in four areas:

1. Embrace a culture of quality

As the onus for regulatory control and compliance falls increasingly to licence holders, companies with a strong culture of quality will prevail. Those with knowledgeable individuals in the QA roles, that have built solid systems, and that have adopted the principles of continuous improvement will be in a better position to navigate the future requirements of the industry.

Culture will play a major role. Companies that have fostered a culture of quality and its associated principles will be more resilient during upheavals and uncertainties. They will be able to respond more effectively than companies that have relegated the responsibility for quality to their QA professionals alone.

To succeed in cultivating a quality culture, a cannabis company must invest properly in the training and cross-training of its people.

2. Ensure the QMS is in control

A QA department that is enabled to focus on prevention and planning instead of reactive decision-making will be the best asset for a cannabis operation. Such an operation requires a robust Quality Management System (QMS) design, adequate resourcing, and ongoing internal compliance by all departments.

The future will necessitate more emphasis on QMS basics: strong change management processes, corrective and preventive actions (CAPA), and quality risk management programs. These programs are critical for ensuring operational risk is minimized at times when the regulatory burden is shifting to the organization.

3. Invest in business-continuity planning and supply chain management

The initial reaction to the COVID-19 pandemic triggered a flurry of vendor changes, most often to acquire personal protective equipment but also for supporting materials (e.g., processing equipment) and functions (e.g., third-party laboratories), as some regular suppliers were no longer able to fulfill their commitments. Sacrifices were likely made in terms of quality, as businesses favoured the long-run benefit of business continuity over near-term quality and compliance.

The QA professionals in our roundtable discussions contend that companies need to critically assess their supply chain for risk, ensure backup suppliers are available, and pre-qualify these backups to ensure business continuity in disruptive times. With proper supply-chain planning, quality is built into the risk management program and does not have to be sacrificed.

To this extent, all the QA professionals we spoke with see the value of investing in business-continuity planning. Many cannabis operators did not have a continuity plan until COVID-19 hit, which was too late. Any plan established since then needs to be reassessed for long-term operations and reviewed by QA to ensure the QMS requirements are taken into consideration.

4. Improve automation to support the QA function

QA professionals with access to an electronic quality management system (e-QMS) and secure data-sharing platforms fared better with some of the reactive and remote requirements demanded in 2020 than those who relied on paper-based QMS systems. The automated tools provided flexibility for oversight, review, and personnel allocation, and facilitated the hosting of remote regulatory inspections. Many QA professionals say their companies are accelerating plans for e-QMSs, and they view this as the single best investment to improve the efficiency of the QA department.

Capitalizing on QA

The QA function is a vital element of risk mitigation and for ensuring the sustainable growth and profitability of the business. 2020 continues the trend of fast-paced change and of struggle for the industry, but management and boards that can capitalize on their organization's QA function will have an advantage in navigating what is to come.

Quality assurance should be an integral part of strategic planning and overall strategy, its professionals' expertise and intimate knowledge of operational systems used for risk management programming and continuous improvement.



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