

2019 Global Risk Management Survey

Life Science industry highlights
October 2019



Foreword

The Life Science industry is an extremely dynamic, R&D-focused, heavily regulated industry that is confronted with more risks than ever before. Considering this backdrop, it is troubling that many organisations participating in the 2019 Global Risk Management Survey stated that they may be less prepared to manage or mitigate their most critical risks.

Aon's 2019 Global Risk Management Survey, the seventh of its kind since 2007, is designed to offer organisations the insights necessary to enable better management of risk related volatility and compete in an increasingly complex business environment. The survey gathered input from 60+ Life Science industry respondents across geographies, covering biotechnology, pharmaceutical, medical devices and other industry sub-sectors.

This Life Science industry specific report highlights key insights from the survey findings and provides an interpretation, validation and viewpoint from Aon's industry experts. It is essential reading for any entity as they evolve their risk register and refine their risk management strategy.

If you have any questions or comments about the Life Science insights, or wish to discuss the results, please contact your Aon account executive and Aon's Life Science Practice Leaders or visit aon.com/2019GlobalRisk.



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Financial Risks (1/2)



GRMS 2019 Insights



Cash Flow /
Liquidity Risk



Commodity
Price Risk

	Cash Flow / Liquidity Risk	Commodity Price Risk
Current risk ranking	10	15
Projected risk ranking in 2022	14	7
Plans are in place to address and manage risk	64%	38%
Reported loss of income from risk (within the past 12 months)	25%	31%

Survey respondents from the Life Science industry rank **Cash Flow/Liquidity Risk** as the number ten risk, while it was ranked eight across all industries. This risk rating reflects that capital availability is a key risk for Life Science companies.

Life Science organisations **require a solid liquidity position as the business is typically time- and resource-intensive regardless of the maturity of the organisation.** Both, access to external funding as well as cash flow optimisation, is therefore considered critical for Life Science organisations. Finding the optimal source of capital is often a vital part for long-term sustainability and growth ranging from the entrepreneur stage/start-up to mature operations.

Most respondents indicate that their organisations have set-up a formal plan to review the risks in relation to capital availability, which includes exchange rate fluctuations and liquidity risks. Furthermore they state that they have experienced losses from these risks. Based on the above, we can see that **cash flow/liquidity risks are often subject to a structured risk management process** as we would expect from companies within this industry where

risk management processes are traditionally well embedded.

Commodity Price Risk is ranked 15 by participants from the Life Science industry, which is significantly lower compared to the overall ranking of seven across all industries. As **Life Science organisations often have a limited exposure to commodity price fluctuation**, mainly in relation to certain raw materials, the lower ranking is not surprising.

Commodity price risk management often involves of a number of stakeholders within a company, including finance/treasury and risk managers. Different risk mitigation strategies, such as price hedging and setting up specific procurement guidelines, require increased internal communication and coordination.

We are **surprised to see this risk ranking so high for this industry, especially the future outlook** which indicates that this risk is anticipated to become significantly more important in the next three years. The cause for the predicted rise of the risk could be connected to the volatile geopolitical landscape which could have repercussions for commodity prices, especially for raw materials of a less common nature.

Financial Risks (2/2)



GRMS 2019 Insights



Capital
Availability/
Credit Risk



Share Price
Volatility

Current risk ranking	20	27
Projected risk ranking in 2022	14	40
Plans are in place to address and manage risk	71%	50%
Reported loss of income from risk (within the past 12 months)	67%	67%

Capital Availability/Credit Risk is currently ranked 20 and is expected to move up to 14 in the risk rankings in the next three years.

In the Life Science industry we typically observe long term business plans, given an average of 13.5 years for a drug to go from concept to approval. Access to capital is a crucial component in corporate growth strategies for most Life Science companies. While R&D strategies require long-term investments, short-term capital requirements may arise in M&A situations or to support the digitalisation agenda. **With increased uncertainty in relation to the regulatory and competitive environment capital availability is expected to become increasingly critical for Life Science companies.**

Finally, **Share Price Volatility** is currently ranked at number 27, while 67% of the respondents indicate that this risk contributed to a recent loss for their organisation and 50% of companies have set-up a plan to formally review this risk. However, this risk is expected to lose in significance in the next three years.

Changing market dynamics such as increased regulatory requirements, changing competitor environment as a result of M&As or new market entrants lead to increased uncertainty and less ability to make accurate financial projections for Life Science organisations, both short and long-term. This creates a potential for increased share price volatility and speculation which in turn will have negative impact on the ability to obtaining capital and financing. While other risks might be more pressing on organisations' risk registers, managing share price volatility should not be neglected. Managing this risk actively could aid in mitigating the impact of unexpected fluctuations. Life Science organisations with a holistic risk management approach will be in a stronger position when unexpected changes occur.

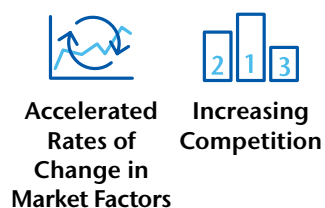


Karl Roquet, Chief Commercial Officer – EMEA for Aon's M&A and Transaction Solutions based in Stockholm/Sweden shared his perspective on financial risks in the Life Science industry.

Market Risks (1/2)



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Current risk ranking	2	5
Projected risk ranking in 2022	1	9
Plans are in place to address and manage risk	33%	36%
Reported loss of income from risk (within the past 12 months)	44%	32%

Accelerated Rates of Change in Market Factors is ranked as the number two risk for Life Science organisations today and is expected to become the number one risk in the next three years.

The **external market environment for Life Science companies is extremely dynamic:** new players enter the market, price competition with generics and biosimilars or other substitution products entering the market, changing reimbursement models and healthcare reforms, digitalisation and scientific breakthroughs change existing business models while Life Science companies need to invest long term into R&D and respond to demands created by the growing and aging population with unhealthy lifestyles.

We expect that the high rank of this risk was affected by two key factors, among others: a) the political environment at the time when the survey was conducted in late 2018 and b) the substantial impact digitalisation and the increased use of data and analytics had on business models in the past three years.

Survey participants from the Life Science industry ranked **Increasing Competition** as the number five risk today and number nine risk in the next three years. The **competitive landscape is changing** as a result of consolidations of large pharmas in recent years. Additionally, new market entrants such as tech giants investing into the Life Science industry, new start-ups and changes in the market powers of suppliers have altered the landscape.

We also see, increasing competition in several therapeutic areas in relation to existing and new products in the pipeline. This is the result of **significant investments in R&D in recent years** which was necessary as many Life Science organisations expect to face substantial competition from generics and biosimilars due to the end of market exclusivity resulting from the expiry of patent protections.

Market Risks (2/2)



GRMS 2019 Insights



Concentration Risk (Product, People, Geography)



Economic Slowdown/Slow Recovery

Current risk ranking	12	14
Projected risk ranking in 2022	12	18
Plans are in place to address and manage risk	36%	9%
Reported loss of income from risk (within the past 12 months)	11%	13%

According to the survey the **Concentration Risk (Product, People, Geography)** is ranked as the number 12 risk, today and in three years time.

This risk appears closely connected to the change in market factors and increasing competition. Large Life Science organisation are all based in the same locations fighting for the best talent to accelerate product developments and launches. In light of this, **concentration risk should be high on life science companies' agenda.**

Finally, **Economic Slow Down/Slow Recovery**, which is the number one risk overall has been ranked 14 by participants from the Life Science industry. A risk that is often not formally reviewed according to survey respondents which makes it less predictable and manageable.

While the Life Science industry may not be as exposed to the overall economic environment as other industries, the

low ranking of this risk gives us cause for concern and we think that **the risk may be underrated by Life Science participants.**

We recommend companies should at least have a plan in place to help mitigate risks from a sharp economic downturn or major geopolitical disruption.



Robyn Garvie (*top, left*), Enterprise Client Leader, based in London/UK and **Marisa Prater** (*top, right*), Head International in Aon Switzerland, based in Zurich/Switzerland, shared their perspective on the market environment and related risks for organisations in the Life Science industry.

Regulation (1/2)



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Regulatory/ Legislative Changes

Current risk ranking	4
Projected risk ranking in 2022	17
Plans are in place to address and manage risk	41%
Reported loss of income from risk (within the past 12 months)	0%

Life Science industry representatives rank **Regulatory/Legislative Changes** as the fourth most critical risk today.

This **risk ranking reflects the broad regulation Life Science organisations are confronted with**. Their production process and products as well as their distribution is regulated in order to ensure product safety while their sales are also subject to the regulatory environment for healthcare funding and financing environment in their core markets. Furthermore, as many Life Science organisations are public companies they are exposed to more regulation and oversights.

For directors and officer of life science companies, the regulatory and legislative corporate governance risk involve the very active pursuit of compliance with securities laws and anti-fraud rules by regulators such as the SEC (Securities & Exchange Commission) and related federal and state entities (i.e. DOJ, AG, FINRA, DOL, etc). The SEC held its annual SEC Speaks conference in Washington, DC on April 8 and 9, 2019. The conference featured remarks from the Chairman and commissioners, discussions regarding current enforcement initiatives

and enforcement priorities for the upcoming year, and an update on litigation, judicial and legislative developments. Chairman Clayton began by emphasising the SEC's three-part mission: (1) protecting investors, (2) maintaining fair and efficient markets and (3) facilitating capital formation. Chairman Clayton declared that the Division of Enforcement had a successful year vigorously policing fraud, resulting in the return of \$794 million to harmed investors. The SEC has incentivised the benefits of cooperation over the last few years. By way of example, in SEC v. Salix Pharmaceuticals, Ltd., which involved financial fraud relating to earnings, Salix self-reported and provided substantial assistance during the SEC's investigation and also self-remediated (including replacing its CEO and other culpable individuals).

So, overall the risk ranking mirrors the strong regulation of the Life Science industry. Any change may have an impact on organisations. Consequently **we would challenge the projected risk ranking in three years time: According to our survey the risk ranking is expected to decrease and end up at rank 17, down from four in 2019.**

Regulation (2/2)



GRMS 2019 Insights



Political Risk/
Uncertainty



Increased Consequences
of Corporate Governance/
Compliance

Current risk ranking	20	26
Projected risk ranking in 2022	22	19
Plans are in place to address and manage risk	17%	63%
Reported loss of income from risk (within the past 12 months)	0%	25%



Kristin Kraeger (left), Managing Director at Aon’s National D&O and Fiduciary Practice Leader based in Boston, MA/USA and **Jayne Minihane** (right), Director in Aon’s Global Broking Centre in London/UK shared their perspective on regulatory risks in the Life Science industry

For director and officers in the Life Science industry the regulatory risk is still very omnipresent. **The reality may be, however, that is surpassed in the mind of the survey participants by headline items like cyber or shareholder litigation.** The fact is, that “event driven litigation” (litigation emanating from a negative corporate event, such as cyber breach or product recall) is a significant driver of shareholder litigation. **Life Science companies remain the number one target of the plaintiffs’ bar and the pace is not slowing down.**

Political Risk/Uncertainty is the number 20 risk according to our survey. From our perspective this is interconnected with the “Regulatory/Legislative Changes” and the “Accelerated Rates of Change in Market Factors” risk.

We note that **Impact of Brexit** was ranked only as risk number 43. This may **not fully reflect the uncertainties around Brexit, yet reflect the size of the market – from a supply chain as well as sales perspective – and the risk mitigation measures implemented.** Large UK and EU based companies, and ROW companies using the UK as their European hub, have

spent a lot of time and money, taken advice and have moved licenses, resources and people around to accommodate Brexit. There may be knock on effects of all this money being spent – resources diverted away from new projects or things being shelved in the short/medium term but the industry seems prepared for the possible implications of Brexit.

Increased Consequences of Corporate Governance/Compliance is ranked as risk 26. Public companies are fairly transparent, and are subject to many governance rules, but private companies are subject to fewer checks and balances. Perhaps the most stark example of the consequence of corporate governance and compliance is the effects of the Supreme Court decision in Cyan and its effects on companies going public, so many of which are life science companies. Life Science companies taking on an initial public offering and the statements they are making in their prospectus documents are now vulnerable to securities law actions in both federal and state court. **Defending multiple litigation, at the same time and in jurisdictions with less developed corporate securities laws is an expanded exposure that today’s newly public companies must address.**

Internal Risk Drivers

Products, Production and Supply (1/6)



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Damage to Reputation/Brand

Current risk ranking	1
Projected risk ranking in 2022	4
Plans are in place to address and manage risk	41%
Reported loss of income from risk (within the past 12 months)	8%

Damage to Reputation/Brand is ranked as the number 1 risk and expected to become a slightly less critical risk to the Life Science industry in the next three years.

It takes time and effort to build a company’s reputation and even more to protect it. Organisations in the Life Science sector have an array of stakeholders including healthcare providers, patients and advocacy groups as well as regulatory bodies to which they have to be a trusted and partner. At the same time they need to convey they are a healthy business for capital providers including share holders and an attractive employer to attract the best talent.

It is a constant balance for Life Science organisations to not only build but maintain a great reputation. Given the nature of the products they create, **customers are extremely sensitive to negative information, especially when it comes to products and product safety.** This means that there is a strong interdependency between reputational and product, production and supply chain risks.

But the interconnectivity doesn’t stop there. As people are a key asset for Life Science organisations, there is also a strong link to people risks as without a good reputation companies will struggle to attract the best talent. Damage to reputation and brand may result in financial loss and liquidity risk increase. Furthermore, damage to reputation and brand also has a strong connection with market and regulatory risks, as non-compliance with regulation could result in a reputational damage.

As the above shows, almost all other risks discussed in this study are interrelated with the damage to reputation and brand risk. So, the risk rating as the number one risk for this industry appears appropriate.



Anne-Christine Fischer,
Global Life Science Practice
Leader for Aon’s Global Risk
Consulting, based in Mulheim/
Germany shared her perspective
on reputation risks in the Life
Science industry.

Products, Production and Supply (2/6)



GRMS 2019 Insights



Failure to Innovate/ Meet Customer Needs

Current risk ranking	8
Projected risk ranking in 2022	11
Plans are in place to address and manage risk	39%
Reported loss of income from risk (within the past 12 months)	9%

Failure to Innovate/Meet Customer Needs is ranked as the number 8 risk and expected to become a slightly less critical risk to the Life Science industry in the next three years.

In general, innovation and meeting customer needs is the strategic objective of Life Science organisations. So, if a company does not meet this objective the continued existence of the company may be at risk.

We have seen the impact of the failure to innovate in pharma patent cliff discussions in recent years. As products come to the end of their patent life, sales of some of the industry's key biologics are eroding or are projected to erode over the next couple of years when biosimilars enter the market. As a result, the **Life Science industry invested significantly into R&D over the past years and expanded their pipeline through M&A deals and created partnerships with traditional and non-traditional players.**

Furthermore, the Life Science industry is also confronted with changing customer needs. Today's customers may have different medical needs as a result of changing life styles but also have demand for different products and new ways of interacting with healthcare providers and the Life Science industry. Patients are interested in transparency, direct communication and clarity on patient pathways.

Overall this risk appears to be underrated as this is closely connected with the overall strategy of Life Science organisations and interrelated with other key risks such as the financial risks, IP, data and digitalisation risk and people risk and should be high up on any Life Science company's risk register.

Products, Production and Supply (3/6)



GRMS 2019 Insights



Product Safety & Pharmacovigilance

Current risk ranking	9
Projected risk ranking in 2022	12
Plans are in place to address and manage risk	61%
Reported loss of income from risk (within the past 12 months)	23%

Product Safety & Pharmacovigilance is ranked as the number nine risk by survey participants from the Life Science industry.

For a Life Science organisation it is not only essential to develop a product that meets customer demands, but also to deliver a product that meets all quality standards – the Good Manufacturing Practice (“GMP”) requirements. As products may be injected intravenous or implanted, high quality standards and product safety are crucial for all organisations in the Life Science industry.

Safety & Pharmacovigilance failure is the failure to protect the public from harm from one’s product. In case a company does not meet these objectives, products may be recalled and plants may be closed by regulators.

Consequently, there is a correlation between the product safety risk and product recall, ranked 19 by survey respondents as well as reputational risks, ranked one in our survey, as well as pharma product liability risks.

The Life Science industry has experienced some of the largest product liability litigations, despite the high degree of regulation and strict approval processes for new products. So, we are slightly concerned that the risk is projected to fall to rank 12 in three years time. Companies cannot take their eye of the ball when it comes to patient and product safety. In consequence, **it is crucial that Product Safety & Pharmacovigilance remain high on a Life Science company’s risk radar.**



Henrik Hansen (top, left), Senior Specialist, Liability at Aon’s Commercial Risk Solutions based in Copenhagen/Denmark and **Jeff Johnson** (top, right), Director Broking, Life Sciences Practice at Aon’s Commercial Risk Solutions based in Philadelphia, PA/USA shared their perspective on product risks in the Life Science industry.

Products, Production and Supply (4/6)



GRMS 2019 Insights



Distribution or Supply Chain Failure

Current risk ranking	3
Projected risk ranking in 2022	2
Plans are in place to address and manage risk	59%
Reported loss of income from risk (within the past 12 months)	38%

Distribution or Supply Chain Failure

is ranked as the number three risk and expected to become the second most critical risk to the Life Science industry in the next three years.

Distribution or supply chain failure can be a challenge to any industry: To the Life Science Industry, a significant impact can result from to the criticality of meeting patient/client demand of life saving products. The Life Science industry takes great pride in their ability to deliver products to the end user in a timely fashion.

Consequently, distribution failures are costly for Life Science organisations. The competitive environment can easily lead to a whole host of negative impacts including, loss of revenue, market share, negative press and increased competition. If an organisation is unable to supply into a market as planned, then it is extremely likely that a competitor drug will be prescribed. Patients generally do not like to change prescriptions, so once a patient is on another drug it may be difficult to revert. Additionally, it can also lead to suits against the company's Directors & Officers. One example would be Genzyme's closing of their Alston manufacturing facility due to the discovery that a virus had contaminated

a bioreactor. This closure led to loss of revenue in the hundreds of millions for an approximate 3-4 month loss of production. It also led to Sanofi picking up market share despite not coming on to the market for a number of years afterwards.

Many companies in the industry have experienced disruptions to their supply chains and at times, due to a shortage of simple raw materials. For example the shortage of specialised ink colours used in packaging have caused unexpected delays or missed customer orders.

Supply failures tend to have a large effect on pharma companies, simply because anything that touches or describes the product is under tight regulation. Hence, the scope for alternatives is limited given the long lead time of regulatory approval.

As the supply chain is becoming increasing complex in the Life Science industry and the dependency on key partners such as single source suppliers or outsourcing vendors is increasing, it's important to create transparency with suppliers to ensure adequate risk mitigation strategies, including financial protection, are in place. A supplier of a supplier could cause an unforeseen unfavourable loss.

Products, Production and Supply (5/6)



GRMS 2019 Insights



Business Interruption



**Natural Resource Scarcity/
Raw Material Availability**



**Failure of Disaster Recovery/
Business Continuity Plan**

	Business Interruption	Natural Resource Scarcity/ Raw Material Availability	Failure of Disaster Recovery/ Business Continuity Plan
Current risk ranking	6	22	23
Projected risk ranking in 2022	6	21	20
Plans are in place to address and manage risk	70%	67%	60%
Reported loss of income from risk (within the past 12 months)	40%	33%	0%

Respondents from the Life Science industry rate **Business Interruption** as the number six risk currently and in the next three years. This risk is closely connected to **Natural Resource Scarcity/Raw Material Availability**, ranked 22, and the **Failure of Disaster Recovery/Business Continuity Plan**, ranked 23.

To the Life Science Industry, a significant business interruption can result in a company's inability to deliver a patient/client demand of life saving products.

Many companies' individual mission statements focus on the Life Science company's desire to ensure the needed supply of either a product or device, is readily available. Given the sensitivity of timing for a medicine to ensure a patient's recovery or a medical device to be in the hospital at time of surgery, the unique exposure for a Life Science company's business interruption impacting these potentially critically needed supplies adds an emotional impact to any disruption to their ability to meet that demand.

Life Science Companies impacted by Hurricane Maria had a common goal: avoid a shortage of their product(s) manufactured in Puerto Rico. While at the same time managing the safety of their employees and

their employees' families, extending support to the local community, protecting the company's assets and restoring operations were all priorities, focus was needed to ensure product delivery was available.

Companies' reliance on safety stock often contemplates the expected customer need resulting from catastrophic events. The unique nature of the compromised public power along with extended time to access some manufacturing sites on the island added another challenge. Life Science organisations, while supporting employees' family needs, had a responsibility to manage product production to mitigate the potential loss if safety stock supplies were depleted. The increased costs to ramp up alternative manufacturing capabilities off the island that may have seen extended time delays for FDA approvals of these sites posed challenges to some companies. The need for generators on the island and the limited sourcing of same on the island added additional costs for companies to expedite delivery through a compromised infrastructure. Fuel on the island was not readily available. An event like Hurricane Maria can differentiate companies that have robust business continuity plans from those that do not. Insurance recoveries vary but the financial impact resulting from this event were significant.

Products, Production and Supply (6/6)



GRMS 2019 Insights



Business Interruption



Product Recall

	Business Interruption	Product Recall
Current risk ranking	6	19
Projected risk ranking in 2022	6	22
Plans are in place to address and manage risk	70%	33%
Reported loss of income from risk (within the past 12 months)	40%	13%

In general, traditional **Business Interruption** events, such as fires, are quite problematic for Life Science organisations. **Their production is an ultra clean environment and smoke or water damage is particularly hard to clean up. In consequence, even small events can have disproportionate impacts due to resulting contamination.** In addition, the regulatory approvals required mean that it is difficult to set up parallel/alternate facilities.

There are also a whole range of non damage business interruption exposures, dominated by regulatory shutdown and cyber events. The impact of a disruption to critical technology can result in large losses. Traditional risk transfer programmes may not adequately provide the needed protection for companies. Recent global ransomware attacks have demonstrated that cyber risk and business disruption extend far beyond data privacy; they represent volatility to the balance sheet. Cyber risk refers to the loss potential an organisation faces by virtue of its reliance on information technology, connectivity and automated processes.

Product Recall is ranked as 19 by representatives from Life Science organisations and expected to become slightly less critical over the next three years.

Product recalls in the Life Science industry are subject to strong regulation and tend to be costly affairs, especially in case of legal actions. Given the experience with recalls and the regulatory environment it is surprising that only 33% of the organisations taking the survey, have a product recall plan in place.



Grant Foster (*top, left*), Managing Director at Aon's Global Risk Consulting UK based in London/UK and **Joanne Quintal** (*top, right*), Managing Director and Property/BI Leader in Aon's US Cyber Solutions team based in Radnor, PA/USA shared their perspective on supply chain, business interruption and recall risks in the Life Science industry

IP, Data and Digitalisation (1/3)



GRMS 2019 Insights



Loss of Intellectual Property/Data

Current risk ranking	11
Projected risk ranking in 2022	24
Plans are in place to address and manage risk	41%
Reported loss of income from risk (within the past 12 months)	22%

Survey respondents from the Life Science industry ranked the **Loss of Intellectual Property/Data** number 11.

One of the core activities of many Life Science organisations is R&D. It can be incredibly expensive to develop a new product and take it to market while the pay off is only realised once the product is launched. A loss of exclusivity can effectively destroy their ability to make a return on investment. As the development lifecycle is often lengthy, IP protection is a key objective for Life Science organisations.

Securing and maintaining a strong, quality IP portfolio is essential for Life Science companies as they pursue their long term business strategy. Loss of key elements of this portfolio could result in huge liability exposure. An example of loss of intellectual property could be through a third party filing an Inter Parte Review (IPR), challenging the validity of one or more patent assets of the company. If successful, the patent asset that they had today may not be valid tomorrow.

Further, given that data is increasingly stored in digital format and shared amongst multiple stakeholders, **the chance that this data could be compromised has increased**

- data corruption or manipulation of critical datasets is also something that companies in the industry are increasingly concerned about. For example, Life Science organisation need to be positioned to provide valid data to regulatory authorities. Should an organisation not be able to share data upon request e.g. to demonstrate batch traceability, regulators may suspend their core products from sale until that data can be provided. Should this involve the need to rerun extensive clinical trials then this cost can quickly mount.

According to the survey Loss of Intellectual property/Data is expected to be less critical in three years.

Aon's Intellectual Property expert disagrees with this survey results. **The IP risk, in his opinion, will continue to increase, particularly with respect to issues like trade secret theft.** He expects that the IP threat from competitors and that of Non-Practicing-Entities will continue to increase.

From a data loss perspective there may be a reduced impact in case of a loss going forward as large organisation become more efficient in recovering data and have an improved data management system.

IP, Data and Digitalisation (2/3)



GRMS 2019 Insights



Loss of
Intellectual
Property/Data



Cyber
Attacks/Data
Breach

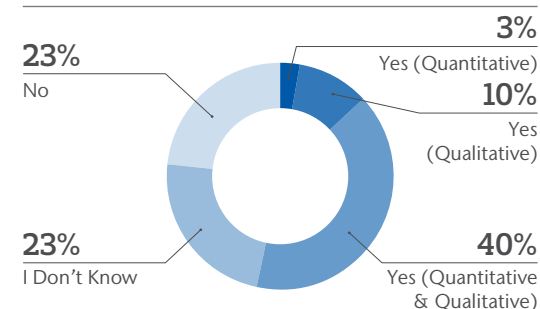
Current risk ranking	11	13
Projected risk ranking in 2022	24	8
Plans are in place to address and manage risk	41%	50%
Reported loss of income from risk (within the past 12 months)	22%	0%

Cyber Attacks/Data Breach is ranked at number 13 for the Life Science industry today according to Aon's survey. The survey response corresponds with our industry insights. From our perspective, **the potential for non-damage business interruption and cyber events impacting a critical supply chain partner have previously been underestimated.** Many large organisations rely on a network of smaller CMO's whose cyber security maturity may be significantly less than their own. Now that Life Science organisations are starting to get a handle on their approach to cyber they are beginning to realise that this 3rd party exposure can be significant. We are encouraged to see that in three year's time the risk is predicted to be in the top ten.

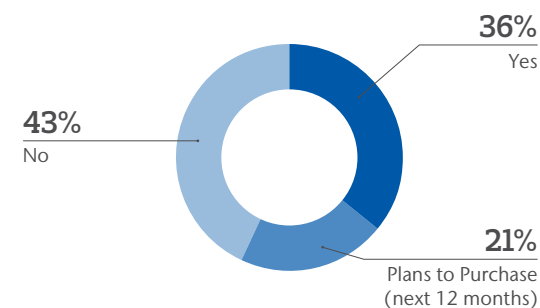
Our survey shows that 40% of organisations claim to have performed a qualitative and quantitative analysis of the risk. However, not all assessments are equal. Whilst it is common for most Life Science organisations to have undertaken a formal security assessment, it is far rarer for them to have undertaken a detailed financial assessment of the risk. Control ratings are useful but only if the organisation is able to identify the critical

technology assets at risk and the financial impact associated with these assets. Otherwise it is impossible to make effective decisions around return on security investment and whether the control maturity is proportionate to the scale of the risk the business faces.

Has your company completed a formal cyber risk assessment?



Does your company have cyber insurance coverage?



IP, Data and Digitalisation (3/3)



GRMS 2019 Insights



Disruptive Technologies/ Innovation

Current risk ranking	17
Projected risk ranking in 2022	3
Plans are in place to address and manage risk	60%
Reported loss of income from risk (within the past 12 months)	0%

Disruptive Technologies/Innovation

is not ranked as a key risk today, but expected to come into focus in the next three years, being ranked as the number three risk in 2022. We see this as a most encouraging sign.

The world is evolving and disruptive innovation is inevitable. **Life Science organisations need to prepare for this eventuality by solidifying a longer-term strategic vision of its products/services roadmap for the long-term health and growth of the company overall.**

The problem companies have is what we could call ‘short termism’. The business environment of market leaders does not allow them to pursue disruptive innovations when they first arise, because they are not profitable enough at first and because their development can take scarce resources away from sustaining innovations (which are needed to compete against current competition). This short term focus on driving current and near term profits takes resources away from development and pursuit of disruptive innovation, which could be seen as short sightedness and might ultimately lead to financial loss.

Further, **the impact of the digital economy may be an underestimated risk - digital wholesalers and direct patient consumption could become more commonplace.** This may bring many typically B2B organisations much closer to the patient and could mean that the business model and sales value proposition may change significantly.



Brian Hinman (*top, left*), Chief Commercial Officer for Aon’s IP Solutions based on New York, NY/ USA and **Christopher Scott** (*top, right*), Senior Consultant in Aon’s Cyber Solutions Team and Life Science Industry Thought Leader based in London/UK shared their perspective on data and digitalisation in the Life Science industry

People (1/5)



GRMS 2019 Insights



Failure to Attract or Retain Top Talent

Current risk ranking	7
Projected risk ranking in 2022	5
Plans are in place to address and manage risk	47%
Reported loss of income from risk (within the past 12 months)	8%

GRMS 2019 Survey respondents from the Life Science industry rank **Failure to Attract or Retain Top Talent** as the number seven risk today.

Failure to attract or retain top talent is a critical risk within any industry, but pertinent to the Life Science industry.

The Life Science industry is being disrupted by new entrants (e.g. health devices, Google, Apple health services), technology and competition from Biotech. In consequence, **we see a true war for talent - the constant pop-up of new emerging start-up biotechs, the emergence of novel sciences and the increasing competition between Life Science and technology organisations for the same talent pool are putting increasing pressure on organisations within the industry.**

In addition, while Life Science organisations in North America and Europe have hired highly-skilled workers around the world for many years, the changing political landscape poses new uncertainties for employers. Brexit for example is creating key challenges for HR managers today.

It is crucial that Life Science organisations develop strategies to capture the talent required to deliver sustainable and successful growth.

Companies can acquire talent or need to build and retain talent, to secure the innovativeness of the industry. It's critical to get hires right the first time round and engage key talent to remain within the organisation to protect the intellectual property they have acquired e.g. for a specific therapeutic area, compound, product, or indication.

In addition, due to demographic challenges (multi-generational workforce), Life Science organisations will need to review their Employee Value Proposition, especially the social impact of the industry.

People (2/5)



GRMS 2019 Insights



Failure to Attract or Retain Top Talent

Current risk ranking	7
Projected risk ranking in 2022	5
Plans are in place to address and manage risk	47%
Reported loss of income from risk (within the past 12 months)	8%

According to our survey **Failure to Attract or Retain Top Talent** is expected to increase in relevance and projected to become the number five risk in 2022, up from seven in 2019. This result corresponds with our observations of what is happening across the industry.

Many Life Science organisations are increasingly reliant on technology and consequently open roles and the types of people who need to fill the roles, as well as the organisations themselves are now having to change to adapt and the competition for talent is increasing.

Over 60% of organisations are already changing or are expected to change in the next 5 years according to Aon Benefits and Trends Report 2019, meaning that they will have to compete for talent in new sectors. Furthermore, there is also a shift in employee demographics and over 50% of companies do not believe that their benefits packages meet the needs of all employee generations.

Employees' expectations of their working environment are also changing and in order to manage the risk of attraction and retention of talent organisations are reassessing the total reward package of their employees. The most prevalent feature of this found in the Aon benefits and trends report 2019 was around approaches to flexible working hours, wellbeing, better approaches to parental leave and diversity and inclusion.

Consequently, adequate risk management is required and Life Science organisations need to assess the risk carefully. They need to quantify the impact on the workforce and plan for the future. Workforce planning and assessing the readiness for the future will be decisive. To date, almost 50% of survey respondents indicate that they already formally review the Failure to Attract or Retain Top Talent risk which is encouraging but still leaves room for improvement.

People (3/5)



GRMS 2019 Insights



Failure to Attract or Retain Top Talent

Current risk ranking	7
Projected risk ranking in 2022	5
Plans are in place to address and manage risk	47%
Reported loss of income from risk (within the past 12 months)	8%

How do Life Science organisations attract and retain top talent?

Life Science companies do have an advantage at times over other industries due to the mission, vision and purpose of their companies. They are truly in a position to change the lives of patients by evolving medicines, devices and/or treatments to better lives globally.

So, while one could imagine that could be reason enough to attract and retain top talent, the truth is pay, perks and benefits are still important and are also key differentiators that make certain companies more attractive to work for.

It's a risky industry and therefore companies have to pay well to intrigue potential candidates to "take the risks" especially at start up companies, whereas established companies have to pay competitively to continue to strengthen and expand their science with key talent. **Outside of pay alone, candidates and employees are constantly striving for an attractive total value proposition.**

We now have five generations in the workforce, so it's a struggle for companies to tailor perks and benefits to interest all, but it's important and sometimes expected in the space. Career mobility is another key driver to attracting and engaging top talent. Millennials want to know how quickly they can get to that next level, other generations want to clearly see a path of progression forward, laterally and/or diagonally to broaden their skill sets and competencies.

In summary it is clear to see that **attracting and retaining top talent will become an even more critical risk going forward impacted by increasing competition and a changing geopolitical landscape.**

People (4/5)



GRMS 2019 Insights



Merger/Acquisition/ Restructuring

Current risk ranking	24
Projected risk ranking in 2022	14
Plans are in place to address and manage risk	60%
Reported loss of income from risk (within the past 12 months)	25%

Survey participants ranked **Merger/Acquisition/Restructuring** as the number 24 risk today, but it is expected to become the number 14 risk in the next three years.

M&A is pertinent to the Life Science industry, the constant evolution of new companies sprouting up or spinning out keeps this life cycle of the industry moving. While there were years in the industry where M&A was hot, then years where it was not, whether due to tax implications, negative industry sector pressures, regulations and legislation not making it easy, whatever it may be there will always be ebbs and flows to M&A activity, but it will certainly never go away within the Life Science industry.

Its important to note that there are benefits to M&A within the industry. M&A can aid in expediting the science and potentially bringing helpful drugs, devices or therapies to patients more efficiently.

Skills, innovation and technology are all important elements of the Life Science industry and it is crucial that HR are consulted early on in any M&A project.

In many cases it is often much further down the line in M&A projects where they are questioned on the employment contracts or pension arrangements of employees. Every deal in Life science will be a “Talent Deal“ but people issues do not make the top agenda of many deal makers.

In many Life Science organisations the skill base is an important feature of the transaction and it is therefore important that HR is involved to focus on the people aspect of any M&A deal.

People (5/5)



GRMS 2019 Insights



Aging Workforce & Related Health Issues

Current risk ranking	28
Projected risk ranking in 2022	N/A
Plans are in place to address and manage risk	40%
Reported loss of income from risk (within the past 12 months)	0%

Globally, the biggest conditions influencing private medical insurance claims include high blood pressure, obesity, poor stress management and high cholesterol – so individual lifestyle choices make a real difference.

The continued rise of corporate insurance costs due to factors such as ageing populations and poor lifestyle habits, is more important than ever to help employees take an active approach to their health.

Life Science organisations are known to offer rich benefits packages and increasing cost of health to organisations is no longer something that employers can ignore.

This presents an opportunity: by rolling out targeted initiatives, there's every chance companies can reduce the number of claims, and offset the rising costs – while looking out for their employees' wellbeing too.

In consequence, **employee wellbeing is an increasingly important topic for many Life Science organisations with over 95% of companies recognising the correlation between employee health and performance.**

These market observations match with the survey insights, where **Aging Workforce & Related Health Issues** was ranked number 28. However, survey respondents did not select the risk as critical when forecasting the risk landscape in three years. We would argue that this risk is expected to remain among the key risks of Life Science organisations and should continue to be a key focus of HR risk management.



Meaghan Piscitelli (top, left), Associate Partner, Global Life Sciences at Radford (an Aon company) based in San Diego, CA/USA and

Suzanne Galbraith (top, middle), EMEA Health Solutions Leader in Aon's Health Solutions team based in London/UK and

Piotr Bednarczuk (top, right), EMEA Head Strategic Advisory in Aon's Strategic Advisory (Inpoint) team based in London/UK shared their perspective on people risks in the Life Science industry.

Risk Management Practice

Risk Identification and Assessment (1/2)











Please rate how proactive your company is when identifying, assessing, and managing current or emerging risks

Weighted Average **7.06**

		Lowest	
		0	0%
not proactive		1	0%
		2	0%
		3	0%
moderately proactive		4	3%
		5	11%
		6	26%
		7	17%
very proactive		8	26%
		9	14%
		10	3%
		Highest	

moderately proactive to very proactive

Select the primary methods your company uses to identify major risks

	49%	Board/Management Risk Assessment
	46%	Risk Info from Compliance Process
	41%	Senior Management Judgment & Expertise
	35%	Risk Info from Internal Audit Process
	32%	Industry Analysis
	30%	Board/Management Risk Discussion (Other)
	30%	Structured Process for Risk Identification (Enterprise-wide)
	22%	External Reports
	22%	Risk Info from Disclosure Process
	16%	Board/Management Risk Discussion (Annual Planning)
	16%	No Formalised Process

Risk managers in the Life Science industry indicate that almost 50% of the risks are assessed by the company board or management.

As risk advisors to this industry, we have noted the high level of risk awareness at the board level in Life Science organisations. However the entire board may only be involved in the risk assessment in case of specific events, e.g. in case of a large loss, launch of a new product, D&O. Often assessments and decisions are made by the risk manager or the CFO only.

Based on our experience many critical risk management and insurance decisions require a sound business case that is presented to the CFO and ultimately becomes visible to the board.

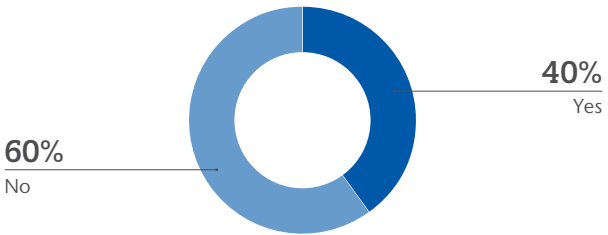
30% of the survey respondents indicate that a structured process for risk assessment is applied.

This finding correlates with our experience with Multinational organisations and Global Large Corporates.

A structured process in risk management typically involves establishing a sound strategy, ensuring alignment of on key goals and objectives, utilising data and analytics to inform decision making, and debriefing following the completion of a renewal to identify success and opportunities to improve moving forward.

Risk Identification and Assessment (2/2)

Does your company measure Total Cost of Insurable Risk?



Currently 40% of the respondents from the Life Science industry indicate that they measure the Total Cost of Insurable Risk (TCOR).

TCOR is paramount to understanding the value of the risk transfer solution.

We see that many risk managers of large organisations regularly apply TCOR to make decisions on their programme structure.

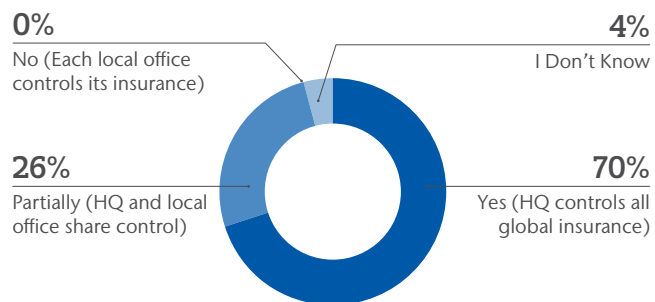
However, some risk managers still focus on premiums and claims and do not consider any indirect or associated costs. Especially in changing insurance market environments it is essential to compare alternative options and reflect all costs in a cost comparison.



Ferran Bellés (*top, left*), Director, Multinational Clients for Aon's Commercial Risk Solutions based in Barcelona, Spain and **Dennis O'Neill, Jr.** (*top, right*), Account Executive, for Aon's Commercial Risk Solutions based in Philadelphia, PA/USA shared their perspective on Risk identification and assessment in the Life Science industry.

Risk Financing (1/2)

Does your company centralise the purchase or control insurance for its global operations?



Please select the lines of coverage that are centrally controlled

54%	Auto/Motor Vehicle Liability	50%	Product Recall & Contamination
38%	Crime	77%	Property Damage & Business Interruption
69%	Directors & Officers Liability	19%	Trade Credit
54%	Employers Liability	54%	Workers' Compensation
85%	General/Public Liability	12%	Other
62%	Marine/Ocean Cargo		

70% of the surveyed risk managers in the Life Science industry indicate that they control insurance for the global organisation.

Major Life Science companies typically have international property and casualty programmes in place with local policies, where the risk manager at headquarter level takes control of global programmes. Regarding people risks, like health & retirement, we often observe a more decentralised approach and local decision making.

A centrally controlled programme can delivery the following benefits:

- It optimises the purchasing capacity of the group
- It allows the organisation to apply a comprehensive Risk Management process
- It keeps control of the risk and insurance information in a centralised way
- It guarantees adequate coverage for all companies nationally and internationally
- It creates easy incorporation of new risks anywhere in the world

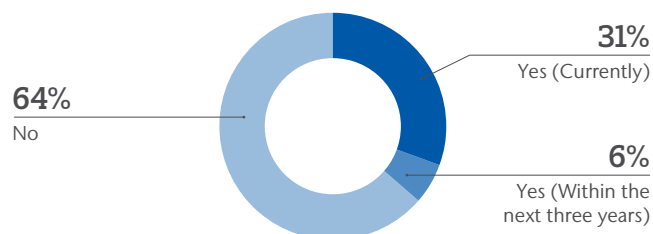
Our experience suggests that larger, sophisticated companies view risk holistically; their risk transfer strategy is measured carefully and focuses on catastrophic protections to establish a controlled programme on most corporate lines - D&O, Cyber, Property, and Liability.



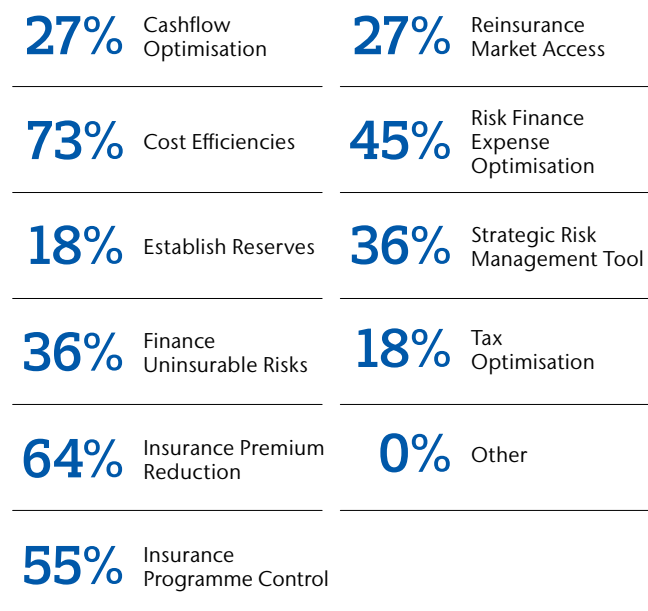
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Risk Financing (2/2)

Does your company have a captive or utilise a cell within a protected cell company (PCC)?



Please select all the primary reasons for your Captive or Cell



At the time when the survey was taken (end of 2018), a very limited number of participants indicated that they would be interested to utilise a captive within the next three years.

For the last number of years, in a soft insurance market environment, insurance and reinsurance captives, as well as a cell within a protected cell company (PCC) may not have been a priority for risk and insurance managers, purely based on a premium/cost perspective. In addition, risk managers were confronted with the uncertainty surrounding the Solvency II regulation in Europe, which led to a stagnation in the set-up of new captives.

However, 2019 renewals have seen drastically increasing rates, if cover is indeed available at all. With the firming market anticipated to continue for a number of years, we have seen an increase in interest in establishing captives, with this expected to continue throughout 2020.

Within the Life Science sector, the new EU regulations surrounding clinical trials has shown companies the benefit of direct-writing EU captives, both from a cost saving standpoint, but also in terms of control of the entire EU insurance process in

the R&D space. Consequently, the change in the insurance market has changed the interest in captive use and therefore the survey response may already be outdated.

Life Science organisations typically establish captives to gain cost efficiencies, according to the survey. Cost efficiencies have been a longstanding benefit for captive owners. So, it isn't a surprise to see this as the primary reason among participants, and, as companies continue to expand their TCoR calculations, this will only increase said efficiencies. While Solvency II regulation has increased the expense bases of running a captive, a well-run captive, reflecting a parent's attitude towards risk management, will promote cost consciousness and efficiency within the parent organisation itself.



Simon Huttley, Senior Insurance Manager for Aon's Captive & Insurance Management and Life Science Industry Thought Leader based in Dublin, Ireland.

Global Risk Management Survey Risk Ranking for Life Science

■ Insurable
 ■ Partially insurable
 ■ Uninsurable

1 Damage to Reputation/ Brand	2 Accelerated Rates of Change in Market Factors	3 Distribution or Supply Chain Failure	4 Regulatory/Legislative Changes	5 Increasing Competition	6 Business Interruption
7 Failure to Attract or Retain Top Talent	8 Failure to Innovate/ Meet Customer Needs	9 Safety & Pharmacovigilance	10 Cash Flow/Liquidity Risk	11 Loss of Intellectual Property/Data	12 Concentration Risk (Product, People, Geography, etc.)
13 Cyber Attacks/Data Breach	14 Economic Slowdown/ Slow Recovery	15 Commodity Price Risk	16 Major Project Failure	17 Disruptive Technologies	18 Rising Healthcare Costs
19 Product Recall	20 Political Risk/ Uncertainty	21 Capital Availability/ Credit Risk	22 Natural Resource Scarcity/Raw Material Availability	23 Failure of Disaster Recovery/Business Continuity Plan	24 Merger/Acquisition/ Restructuring
25 Unethical Behavior	26 Increased Consequences of Corporate Governance/Compliance	27 Share Price Volatility	28 Aging Workforce & Related Health Issues	29 Corporate Social Responsibility (CSR)	30 Personal Liability (Directors & Officers)
31 Property Damage	32 Exchange Rate Fluctuation	33 Third-Party Liability (e.g. E&O)	34 Weather/Natural Disasters	35 Workforce Shortage	36 Inadequate Succession Planning
37 Tech Failure/System Failure	38 Failure to Implement/ Communicate Strategy	39 Impact of Artificial Intelligence (AI)	40 Environmental Risk	41 Outsourcing	42 Impact of Brexit
43 Off-Label Promotion	44 GDPR Requirements/ Non-Compliance	45 Pandemic Risk/Health Crises	46 Embezzlement	47 Impact of Digital Economy	48 Harassment/ Discrimination (Employment Related)
49 Globalisation/ Emerging Markets	50 Geopolitical Volatility	51 Fraud	52 Outdated Tech Infrastructure	53 Workforce Generation Gaps	54 Terrorism
55 Interest Rate Fluctuation	56 Climate Change	57 Counter-Party Credit Risk	58 Resource Allocation	59 Absenteeism	60 Asset Value Volatility
61 Gender Pay Gap	62 Extortion	63 Work Injuries			

About Aon

Aon plc (NYSE:AON) is a leading global professional services firm providing a broad range of risk, retirement and health solutions. Our 50,000 colleagues in 120 countries empower results for clients by using proprietary data and analytics to deliver insights that reduce volatility and improve performance.

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