



Industry Analytics Report

Regulatory Affairs
Spring 2016



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About Vacancysoft Data

Our data set for this report contains information on 1 700 vacancies. These vacancies were found during normal Vacancysoft operations; duplicates were eliminated and the vacancies were processed according to our proprietary rules.

All of the vacancies in the data set were found between April 2014 and March 2016, and they all came from companies that had posted at least one job before the start of that period. All of the vacancies were based in the EEA or Switzerland. Vacancies from some companies were excluded because it was not possible to produce a consistent data set.



We are delighted to be partnering with Vacancysoft to provide insight on recruitment activity in the Pharmaceuticals sector.

For this report we have been analysing activity in Regulatory Affairs recruitment over the last two years, identifying key trends we are witnessing.

I hope you find it interesting and should you like to know more about current market activity please do contact me on yvette.cleland@clinicalprofessionals.eu

Yvette Cleland
CEO
Clinical Professionals



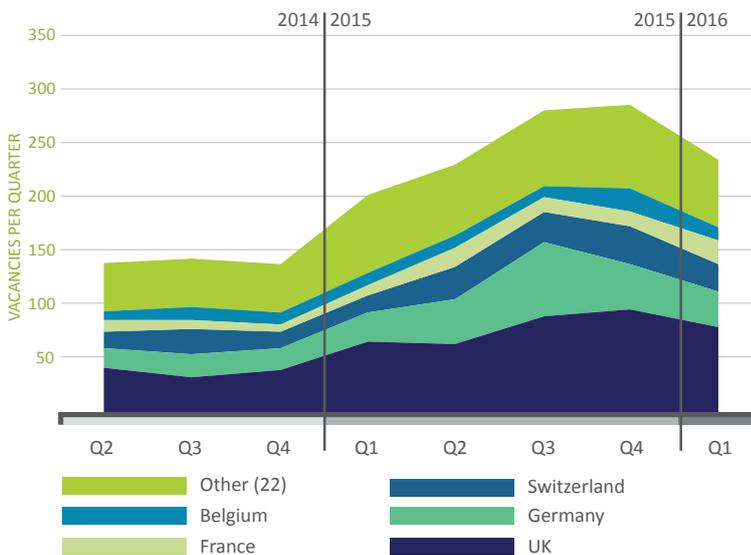
In the 24 months, from April 2014 to March 2016, Vacancysoft gathered 1 711 vacancies in Regulatory Affairs across the EEA and Switzerland. Despite some monthly volatility the data showed strong and sustained growth over the period. This resulted in a year-on-year increase in regulatory vacancies of 66%. Much of this was attributable to an exceptionally strong 2015 following a fairly flat middle and end to 2014. The start of 2016 saw a noticeable drop of 18% in Q1, perhaps indicating the beginning of a slow down in the market.

Looking at individual countries we see that the UK remains the dominant force in Europe with 30% of all regulatory vacancies and an average annual growth rate of 77%. The next largest market, in terms of share, was Germany with 16% following a year-on-year increase of 119%. Switzerland (12%), France (6%) and Belgium (6%) complete the top five.

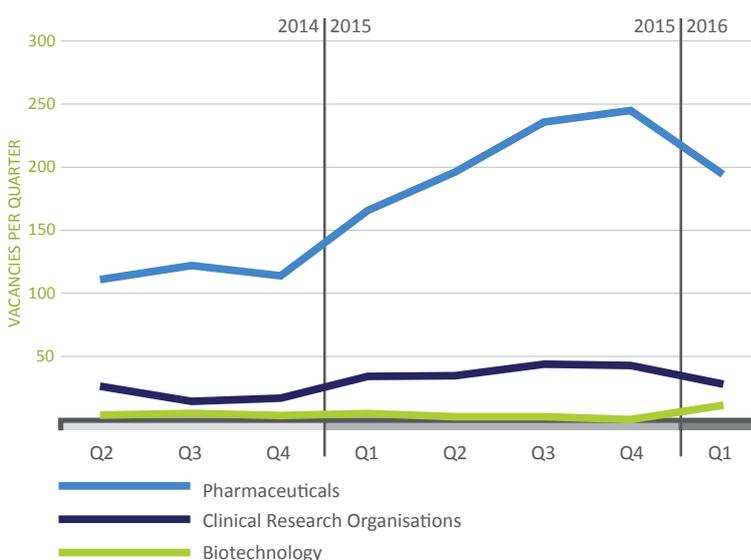
Vacancies in the traditional Pharmaceutical sector make up the vast majority of the total, 84%. Almost all of the remaining vacancies are with CROs (15% of the total). Of all of these vacancies, nearly three-quarters (72%) were general Regulatory Affairs roles, with CMC (10%), Clinical Submissions Specialists (7%), Regulatory Documents (6%) and other specialisms accounting for the rest.

The regulatory landscape has continued to evolve in response to product safety, regulatory compliance, new technologies, improved understanding of disease states, stakeholder and customer needs and global imperatives, with new and increasing regulations, regulatory guidance and oversight. Regulatory professionals in the biopharmaceutical industry occupy a central and pivotal role to all the functional groups. The global Active Pharmaceutical Ingredients (API) market is expected to reach USD 206 billion by 2020 from USD 150 billion in 2015. Factors such as the increasing incidence of lifestyle and age-related diseases, increasing prevalence of cancer across the world, technological advances in API manufacturing, emerging markets for biosimilars, and increasing scope for highly potent active ingredients are driving market growth, which of course drives growth in staffing in this specialist space.

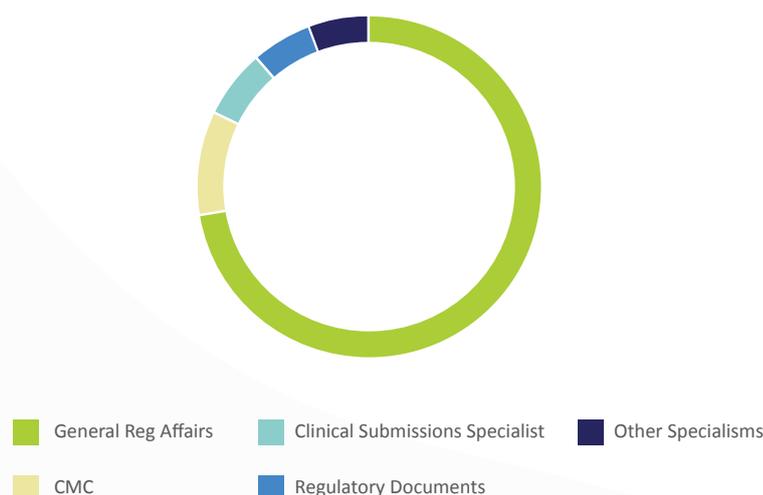
European Regulatory Affairs Vacancies
APRIL '14 TO MARCH '16



European Vacancies by Sector
APRIL '14 TO MARCH '16



European Vacancies by Role
APRIL '14 TO MARCH '16



Geography Analysis

Of the 27 European countries where Regulatory Affairs vacancies were identified, 70% originated from just five key markets, the largest being the UK with 30%. In terms of growth Germany saw the highest year-on-year gain to March 2016 with an increase of 119% followed by the UK with 84%. Switzerland, France and Belgium all more or less tracked the European average with 66%, 68% and 62% respectively.

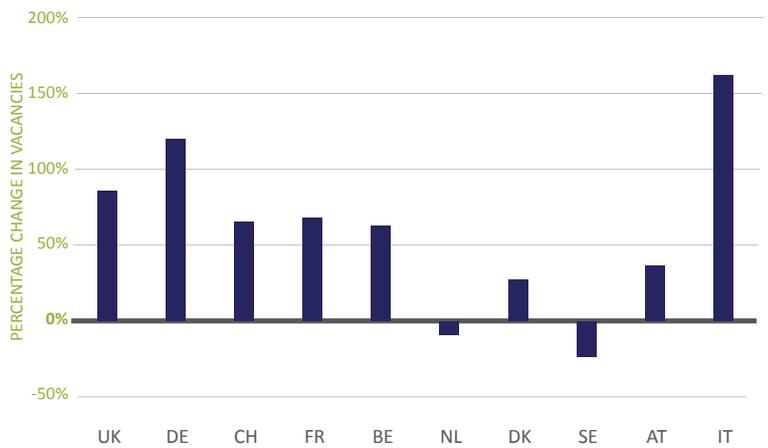
Looking at the broader European market we see several countries with significantly different growth figures. Of those only two major markets saw a drop: the Netherlands, with 5% market share, and Sweden, with 3%. At the opposite end of the spectrum was Italy, with an impressive 162% increase driven by a strong surge in activity by PPD.

Breaking down vacancies to the city level, we see some interesting results. Basel had the highest number of vacancies, with half of all Swiss openings, representing 6% of the total market. This was followed by Cambridge (5%), London (4%), Harlow (3%) and Holzkirchen in Germany (3%). Interestingly the biggest year-on-year growth was seen in Holzkirchen, with an incredible 288% increase, and Macclesfield, with a 200% rise, driven by high vacancy numbers at Hexel and AstraZeneca respectively.

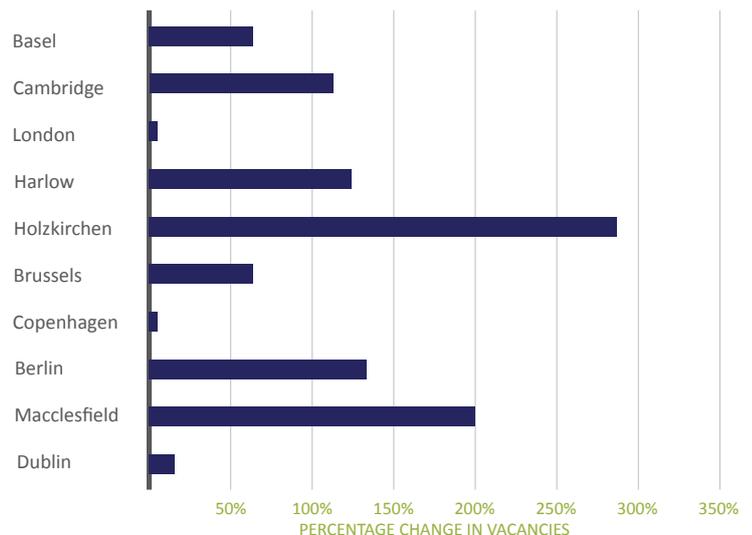
Touching briefly on the UK market, one trend stands out: the sizable shift in vacancies away from the Greater London area, which remained fairly static, to the South East, East and North West of England, which all saw an increase of about 120%.

There is no surprise in the surge of vacancies in Regulatory Affairs in Cambridge, UK. Over recent years, a huge number of technological startups have appeared in Cambridge, driving this cluster of expertise often referred to as "Silicon Fen", which makes Cambridge a global player in multiple scientific industries, in particular biotechnology. As this core region continues to mature the volume of vacancies increases. The Biohub at Alderley Park, Macclesfield, has attracted a vast level of new startups accounting for an increase in roles. With the number of large HQs in Basel the continued growth in positions here is also no surprise.

Year on Year Growth in 10 Most Active European Markets



European Vacancies by City
APRIL '14 TO MARCH '16



UK Vacancies by Region
APRIL '14 - MARCH '15 vs APRIL '15 - MARCH '16



Unsurprisingly, 72% of all vacancies were in 'general' Regulatory Affairs, and the majority of these were in traditional Pharmaceutical companies, where they accounted for 76% of openings. These generalist positions saw relatively low year-on-year growth of just 38%, well below the 66% average, suggesting a shift toward more specialised roles. This was particularly acute amongst CROs, which saw a drop of 35%.

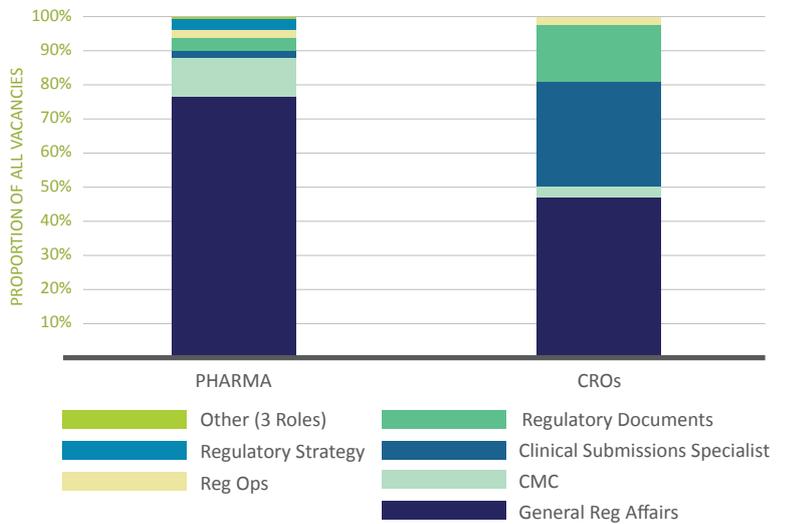
When we compare vacancies between CROs and Pharmaceutical companies we see some clear differences. CMC roles represent a much larger proportion in traditional Pharmaceuticals, where they are the second largest segment with 11% of vacancies, than in CROs, where they only account for 3%. The second largest segment in CROs, however, is taken by Clinical Submissions Specialists with 31% of vacancies. Much of this can be attributed to the surge in activity seen by PPD, where 60% of vacancies were in Clinical Submissions Specialist positions.

We see a similar result with Regulatory Documents roles. Despite seeing more vacancies in terms of total numbers in Pharmaceutical companies, Regulatory Documents roles represent a significantly larger proportion of openings in CROs.

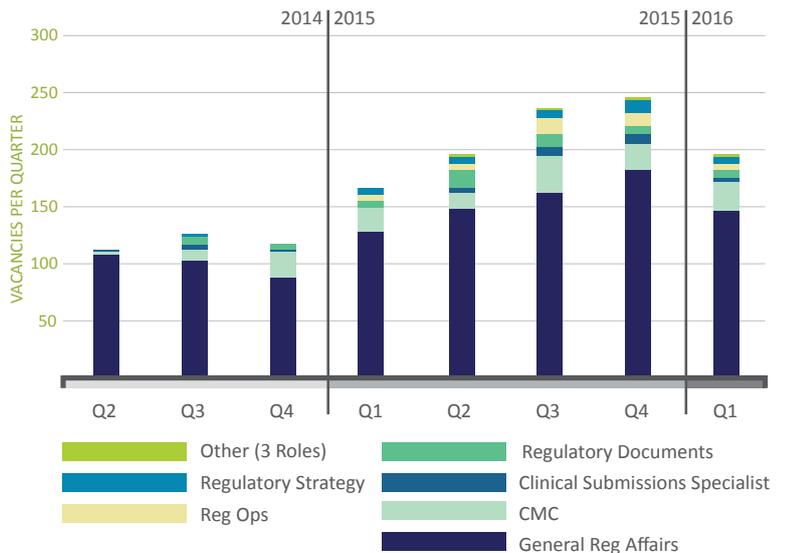
The findings of the report resonate well with the experiences of the Regulatory Affairs Perm team here: we have found that the majority of vacancies have taken a shift from previous years, from CROs to more Pharma and Biotech companies. The types of Regulatory vacancies have tended to be more generalist with most vacancies covering LCM and Post Marketing/Approval. We have however seen a shift from the level of vacancies, moving from mid-level to more Senior Manager, Associate Director, Director and Senior Director roles.

From a contract perspective our vacancies have surprisingly come predominately from CROs, with the types of vacancies and demand coming for candidates with submissions, CTA and operational backgrounds. The levels of vacancies correlate well with the report, with the majority of them being Associate – Project manager level.

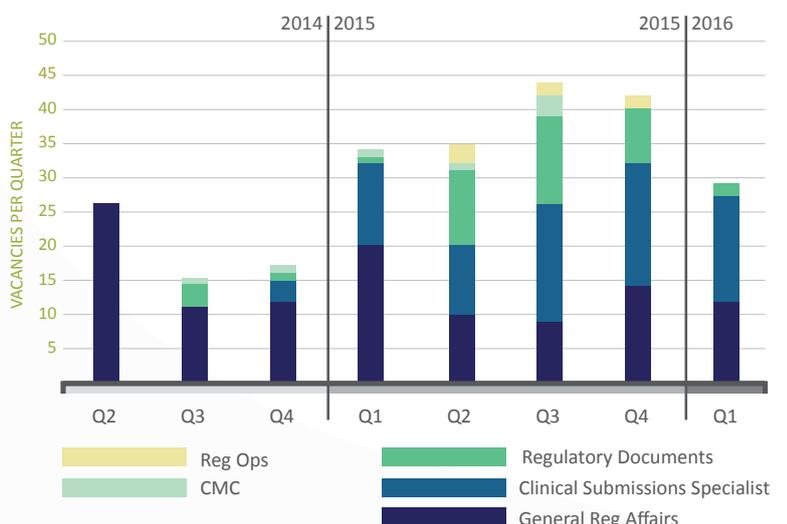
Relative Proportion of Vacancies by Role
APRIL '14 - MARCH '16



Roles in Pharmaceuticals
APRIL '14 - MARCH '16



Roles in CROs
APRIL '14 - MARCH '16



Over the 24 months to March 2016, vacancies were identified at 123 companies; 109 traditional Pharmaceuticals, eight CROs and six Biotechnology companies. The vast majority posted relatively few openings, and the top 10 most active companies accounted for over half, 54%, of the total.

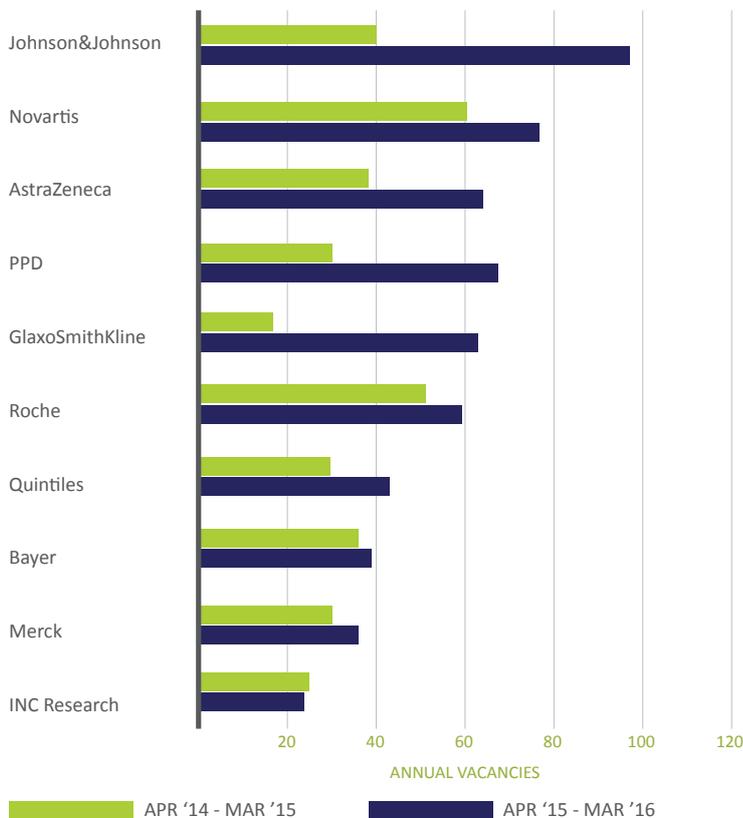
The ten busiest companies comprise seven Pharmaceuticals, with Novartis (8%), Johnson&Johnson (8%) and Roche (6%) leading the way, and three CROs, the most active of which was PPD, with 6% of the market.

In terms of year-on-year changes GlaxoSmithKline, Johnson&Johnson, and PPD saw the biggest increases. INC Research was the only company in the top ten to show a drop in vacancy numbers, and that drop was only 4%. The remainder showed below average to moderate growth varying from 8% for Bayer to 68% for AstraZeneca.

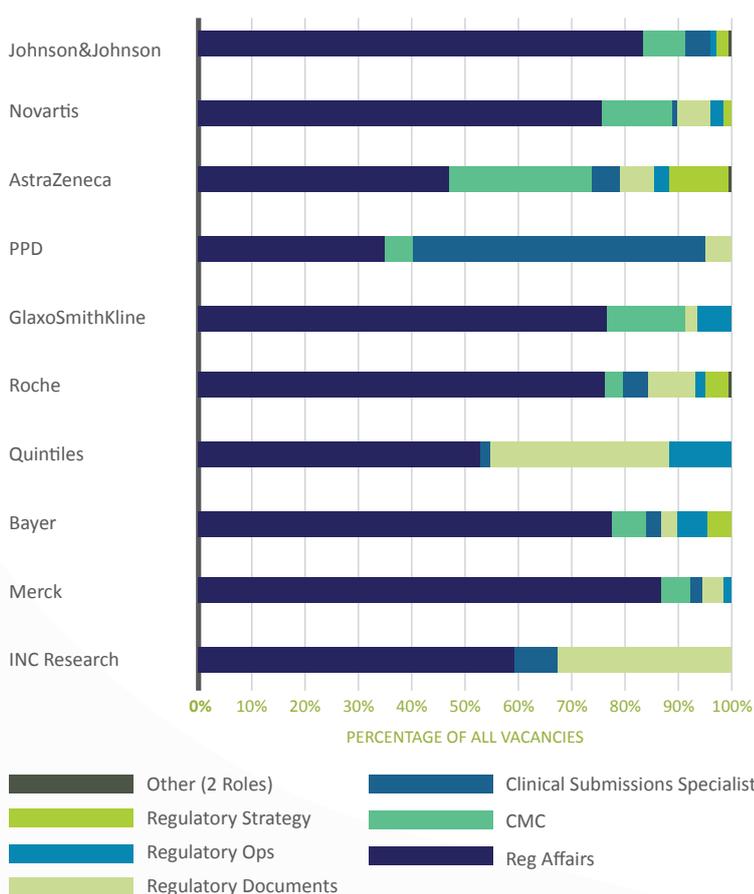
Looking at the location of their vacancies in the last 12 months, most companies were most active in the big five European markets. Only Quintiles and PPD had less than half their openings in these countries.

Managing the complexities of a harmonised, increasingly complex, global regulatory landscape has become the prime concern for any pharmaceutical organisation, which also impacts staffing and getting the best staff. Indeed, those organisations who successfully implement an effective regulatory compliance framework are likely to be able to differentiate themselves from their peers and attract the best candidates in an increasingly skill-short market, as they articulate to patients the rigor in the development, on-going manufacture and use of drugs, to deliver improved health and quality-of-life outcomes. This will not only help drive value, but will provide an opportunity to address some of the reputational issues that are so often raised against the pharmaceutical industry, and improve their own company profile and attract the best staff to fill critical roles in Regulatory Affairs.

Year on Year Activity 10 Busiest Companies



Relative Proportion of Vacancies by Role, 10 Busiest Companies APRIL '15 - MARCH '16



Clinical

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Clinical Professionals is Europe's leading life science staffing business offering outsourced solutions via Functional Service Provision (FSP) and traditional, high quality staffing solutions. Detailed market research carried out in early 2013 found that 95% of hiring managers rate Clinical Professionals as consistently superior in quality, speed of response, staff retention and communication. In addition to this, nine out of ten customers rate the company as their most trusted partner.

Clinical Professionals have developed a highly comprehensive understanding of a broad range of specialist functional disciplines within the pharmaceutical industry. Our knowledge-base has its foundations in an unrivalled blend of industry experience combined with a commitment to investing in training and development. We have specialist teams dedicated to recruiting within the various pharmaceutical sectors for permanent, contract, interim, FSP and freelance vacancies. Clinical Professionals offer a variety of services for both candidates and clients, including our CP FSP model, offering clients the opportunity to outsource the recruitment of a whole team whilst retaining control of the monitoring function in-house.

What we do:

Our Service Capabilities across all European Countries include:

- Contingency permanent recruitment
- Contract recruitment – freelance and PAYE via Clinical Professionals/Only Medics
- Search and selection permanent recruitment
- Specialist 'project-based' interims via Clinical Professionals/Only Medics
- FSP outsourced teams across Europe

Clinical Professionals has launched their **2016 European Salary Survey** to determine the salary and benefits for each sector of the UK Life Science industry.

The Survey will analyse salary and benefits for each sector of the European Life Science industry, and follows on from the success of our previous pharmaceutical salary surveys.

Contact us for more information on salariesurvey@clinicalprofessionals.co.uk

UK Office
33 Blagrove Street,
Reading, Berkshire,
RG1 1PW
t | +44 (0)118 959 4990



EU Office
Ground Floor,
11-12 Bouverie Street,
London, EC4Y 8DP
t | +44 (0)207 822 1710