MSI Pharma

Experts in pharmaceutical, medical device and life sciences recruitment

CONTENTS

WHO DO WE RECRUIT?

CLINICAL

CRA
CPM
CTM
Clinical Director
Medical Writers (CER, Technical, Scientific)

REGULATORY

Regulatory Affairs Specialist
Regulatory Affairs Manager
Regulatory Affairs Associate
Regulatory Affairs Director

MEDICAL

Medical Device Vigilance Specialist / Experts / Physicians (All Levels)
Clinical Development Physicians (All Levels)
Medical Affairs Specialist / Experts / Physicians (All Levels)

QUALITY

Quality Engineer
Quality Assurance
Quality Control
QMS Consultant
Quality Project Manager
Design Quality Engineer
Supplier Quality Engineer

CSV & AUTOMATION

CSV Specialist Data / Infrastructure / Compliance
Validation Consultant
LAB Validation (LIMs)
Automation Engineer
Equipment Engineer
Software QA Automation
Cloud Automation Engineer
Test Automation Engineer
RIM's IDMP
Test Method Validation

ENGINEERING

R&D Engineer (Research and Development Engineer)
Mechanical Engineer
Project Manager / Engineer
Staff Engineer / Principal Engineer / Senior Engineer
Research Engineer
Research Scientist
Software Engineer
Electrical Engineer

QUALIFICATION

- Referencing all candidates (manager and peer)
- Helping conduct initial interviews
- Networking events, globally with guest speakers (EMEA & US)
- Industry networked events (TOPRA, DIA, Partners in Clinical Trials, BioMED, MEDICA, PhUSE)
- Return to Home (hosting networking events outside of country to find out what it would take native speakers to return home for projects)
- Global research team (a team of researchers to map out countries with teams specialist in particular niches and countries)

OUR GLOBAL REACH IN 2018:

- Placed in 48 countries (contract and permanent)
- Access to Linkedin Recruiter
- Access to Pharma job-boards for postings and CV searching (EMED, Pharmiweb, Indeed, PharmaJobs, Biospace, Medzilla)
- Placed in 6 out of 7 continents

CASE STUDY
BSI

BSI has been a leading notified body in the European Medical Devices System for over 25 years.

Immediately after the 2016 EU referendum result, they triggered their pre-prepared contingency plan to establish an alternative notified body in the Netherlands. This was successfully designated under the existing 3 Medical Device Directives **(MDD/AIMDD and IVDD)** at the end of 2018. The strategic importance of this second office was to ensure continued market access to the European Medical Devices market for their clients despite Brexit.

As a UK based notified body, they had an almost **non-existent work force in the Netherlands with no track record of recruiting in the country**. They had three recruitment partners that had supported them for over 10 years each and worked on a basic contingency model, with the **average time to hire being >9 months.**

MSI Pharma was established as a partner in 2016 to support them with their ambitious growth plans in the country. We partnered them on a retained model and took responsibility for **1/3 of their recruitment efforts**. Since 2016, we have **reduced their time to hire from >9 months to an average of 6 weeks**.

Our medical device team partnered all areas of their business: Orthopaedics, Dental, Ophthalmology, Soft Tissue, Wound Care, Combi Devices, Medicinal, Vascular, Active Implantable, Active Devices, Microbiology, Contraceptive, Tissue Sampling and IVD.

We were tasked with recruiting:

- **Auditors**
  - Experienced auditors from other notified bodies
  - R&D, testing, manufacturing professionals from medical device manufacturers who want a career as an auditor
  - Quality professionals with experience in quality management systems
- **Technical Specialists**
  - R&D, testing, manufacturing professionals from medical device manufacturers who want a career with a notified body
  - Engineers/ Scientists with full product lifecycle experience – bought multiple products on to EU market
- **Certification Specialists**
  - Regulatory specialists from medical device manufacturers
  - Regulatory specialists from notified bodies

- **Clinical Evaluation Specialists**
    - Medicine background and have moved into medical devices as a clinical specialist writing and reviewing clinical evaluation reports

Without the placements of the professionals above into the Netherlands, BSI would not have been successful in their designation of their Dutch entity. This recruitment was pivotal in their business strategy and BREXIT contingency planning. They are now the only UK based notified body left in the market and they continue to grow. They have capitalised on their competitors leaving the market by increasing their client numbers and their headcount. Their clients are now fully secure in the pursuit of MDR and IVDR designation over the transition and implementation periods respectively.

Further to the successful recruitment campaign that we led between 2016 and the end of 2018, we were tasked with a new campaign in January 2019.

Due to BSI's aggressive growth plans for 2019 they identified that t**hey needed 60 US based medical device auditors**. They needed our support and for us to come up with a strategy.

Our first port of call was to go into the business and look at the role of an auditor and the team within **BSI USA**. We quickly identified that the retention issues were connected to the strain on their **auditors being on the road for 100% of the time** – therefore not being utilised. Also, with an **opening salary $15,000 lower than their nearest competitor it positioned BSI as unfavourable than to their competitors**.

We embarked on a comprehensive market research assignment to gather market data on their major competitors, travel requirements and salary bandings for their auditors. We then analysed the competitors' application ratios per role against those of BSI and found that they were **on average 3% higher**, resulting in them losing out on around 24 candidates.

Upon completion of this piece of work, we then presented to senior members of the talent team and HR. We demonstrated that, if they were to align themselves with their competitors in terms of salary bandings and travel requirements, this, coupled with their market leading reputation, would enable them to position themselves as the employer of choice.

Interview days were held in various US locations where many candidates attended together for their second stage interviews. We had candidates of all levels of experience and backgrounds attend with the idea that the management could assess to value each person and skill set could bring to the business.

Only at this point did the recruitment levels increase.

In October recruitment was put on hold with only 7 positions remaining. This is purely due to the huge number of new starters coming into the business and without BSI having the resources to train them all quickly enough.

Our latest task is to identify training personnel for their business to get their new staff up to the level required quickly.

Recruitment for auditors will commence again in January.

CASE STUDY - DEPUY SYNTHES (PART OF THE J&J GROUP OF COMPANIES) QUALITY, REGULATORY, CSV & ENGINEERING

BACKGROUND

In 2012 J&J acquired Synthes to merge with their existing Orthopaedic Medical device brand, making them the largest orthopaedic medical device company in the world.

In 2012 Depuy Synthes received a significant FDA warning letter focused around the handling of device related complaints. The subsequent internal investigation uncovered much wider issues involving almost all areas of the QMS and in 2013 triggered one of the largest remediation programs the Medical Device industry has ever seen.

J&J Launched a global remediation program designated GQRP, covering almost every facet of the Depuy Synthes business, which would require a huge amount of resource that their current supply chain wasn't set up to provide. Enter MSI Pharma.

After the initial phase of the project had commenced, and with the volume of requirements set to increase, **MSI Pharma made the decision to recruit a designated Delivery Manager to oversee the project and ensure we were able to maintain our high standards** whilst also working at the pace needed to satisfy Depuy Synthes, without sacrificing our other existing clients.

The Delivery Manager joined the business in early 2014 and over the next 2 years ensured a fill ratio of over 20% (against a standard SLA requirement of 10%) competing with over 15 agencies.

The table below provides details of the scale and skill sets that were covered during this project:

Vertical Areas	Key Skill Sets & Roles	Number of Roles	Number of Fills
Engineering	Product Development	29	9
Engineering	Manufacturing, process validation, product transfer and Test method validation	42	10
Computer System Validation	Computer System Validation & automation	27	10
Regulatory Affairs	Specialist, technical writers, submissions specialist, DHF experts & project managers	18	4
Quality Assurance	CAPA specialist	10	4
Quality Assurance	Complaints Handling experts/Field actions specialist	21	5
Quality Assurance	Quality assurance specialists – including Sterility, supplier quality & design quality	57	14
Project Management	Project/Program & leadership roles	11	2
Other roles	IT business analysts, SAP experts, IT Support, PMO professionals, Wet room staff, procurement, Finance & supply chain staff	102	12

*These placements were achieved whilst competing against a preferred supplier list of 15 agencies

The below table details our KPI performance against the clients service level agreement during the GQRP program:

Key performance indicator	Kelly OCG/Depuy Synthes requirement	MSI Pharma Actual
CV submission	72 hours	22 hours
CV to interview ratio	4:1	3:1
Interview to offer	3:1	2.2:1
Offer to acceptance	3:2	1.22:1
Fill %	10%	22.08%
Assignment completion %	95%	97.5%

OUR SOLUTION METHODOLOGY

- Vertical markets: our delivery consultants were assigned to skills verticals enabling them to develop multilingual talent pools ready to deploy at short notice to new requisitions as the client needed.
- Speed: due to the constant focus on developing talent pools coupled with our team's in-depth industry knowledge we were able to cut the standard CV submission time from 72 hours to less than 24 hours and often less than 12 hours. This enabled the hiring managers to act much quicker and cut resource deployment timeline down significantly.
- Engagement: during the peak hiring periods the Delivery Manager & the divisional manager made regular visits to the key sites, meeting with key stakeholders, deployed resource and our local compliance team to ensure any future needs were identified early so new talent pools could be developed, any resource issues were rectified rapidly and to ensure all communication was clear and concise.
- Focus on quality: our consultants were targeted not on volume but on quality based KPIs including CV to interview ratio, Interview to offer ratio and offer to acceptance. This ensured that the hiring managers had to invest a minimal amount of time reviewing CVs as the ones submitted were all relevant.
- Trust based process efficiencies: as we built a trust-based relationship with the key program stakeholders they were able to make process adjustments which resulted in significant time savings. The main time saver was switching from a 2-stage interview process including a face to face interview to a one stage, telephone or video-based interview.

KEY STATS & ACTIONS

- To fulfil the large volume of needs for the Program we sourced candidates 17 countries with 24 nationalities.
- MSI Pharma developed a relocation system enabling us to deliver resource on time from a wide range of countries so that we weren't limited to the local area.
- MSI Pharma opened a local office to ensure control and efficiency of our processes.

RESULT

Over the initial period of GQRP, Depuy Synthes hired over 300 external contractors in Switzerland alone, which enabled them to deliver the successful completion of the main program goals on time.

During the key 2.5 year period MSI Pharma was recognised as the best local supplier twice and later recognised on a global level through Kelly OCG (J&J MSP partner) as one of the best 30 suppliers against a total global contingent worker supply chain of 10,000 agencies for our continued support.

Testimonial – Local Vendor Management lead for KellyOCG onsite at Depuy Synthes during GQRP

"I always enjoyed working with Ed and his team as their communication and service levels were outstanding. We recognised them on a number of occasions as our top Supplier, shown by the fact that they easily filled difficult roles that our other partners could not. This was no doubt helped by their large professional network, their enthusiasm for the sector, their ability to always ask the right questions as Subject Matter Experts, and their willingness to go the extra mile. I would have absolutely no hesitation recommending Ed and MSI as a partner."

MEDICAL CASE STUDY - UCB CASE STUDY COMBINATION DEVICES - RISK MANAGEMENT

BACKGROUND

UCB developed a new combination product and as a result needed to hire an experienced professional to set up the internal systems and processes around Risk Management. UCB had spent a significant amount of time trying to find a permanent solution with the internal talent acquisition team before approaching MSI Pharma to support them.

MSI PHARMA – OUR SOLUTION

When we were engaged, the **project was at risk of being delayed due to the absence of a successful hire** for this role. The **UCB team had spent 4 months focussed initially on finding candidates** purely from a combination device background that had significantly limited the possible field and they had exhausted their search.

We did some initial research and **reverted-back to them 36 hours later** with a twofold strategy to provide them with the required skills.

Firstly, we suggested broadening the search to people with Pharmacovigilance and Medical Device experience, rather than just Combination Device experience. We felt that in the absence of candidates with the levels of Combination Device experience UCB wanted, someone with experience in both Pharmacovigilance and Materiovigilance would be able to fulfil the role after an initial period of research into the intricacies of the combination device regulatory requirement. Starting from a blank system, this person needed to have experience in both a clinical and post market environment for Pharmacovigilance as well as risk management and Materiovigilance experience – this proposal was accepted, and the below brief was developed.

BRIEF

- Minimum of 7 years of experience in the medical device industry within medical device surveillance or related functions (10 years preferred)
- Minimum of 7-year experience in Pharmacovigilance (10 years preferred)
- Expert understanding of device and ideally combination product regulatory requirements (not limited to but primary focus on US, EU, JP).
- Medical Degree
- Good leadership, managerial and organizational skills
- Strong knowledge of both ISO 13485 & 21 CRF part 4

The second part to our strategy was designed to meet both the short term and long-term needs of the project – hire a senior interim resource to set everything up, then follow this with a slightly more junior permanent option with an extended education and handover process to bring them up to speed on the new processes & systems.

This strategy was found to be acceptable and as a result we were able to leverage our global network to find an interim solution within 7 days – the successful candidate was referred to us by a previous contractor based in Switzerland and started on the project 22 days after our initial briefing on the project.

Once the initial resource was on site with UCB, our perm team them commenced a project to map out all potential candidates within the EU (this was at the clients request as they didn't want to provide a work permit) in order to source suitable option for the long-term permanent solution.

The candidate started with **UCB and went through an intensive 3-month training and onboarding process delivered by the initial interim hire**.

CLINICAL CASE STUDY
BLUE EARTH DIAGNOSTICS (BED) - SENIOR MEDICAL DIRECTOR - CLINICAL DEVELOPMENT

BACKGROUND

Blue Earth Diagnostics are a niche company set up by a small group of ex-GE executives to develop molecular imaging technologies to address unmet clinical needs, and reliably inform diagnosis and treatment decisions.

BACKGROUND

BED had decided as part of the growth strategy to hire an interim Head of Clinical Science to support the incumbent Chief medical officer in getting the clinical program started. As they had an existing relationship with another agency, they had given that agency exclusivity over the role for an initial period of 8 weeks. During this period the other agency had provided BED with several candidates that had strong pharmaceutical clinical development background but lacked experience in Diagnostics & Imaging.

Entering the last 2 weeks of the exclusivity MSI Pharma approached BED about the role as we had been informed by our network of the position.

MSI PHARMA – OUR SOLUTION

BED explained the exclusivity agreement and MSI Pharma suggested we run a parallel search so that in the event the other agency failed to deliver we would be able to deliver candidates without further delay.

BRIEF

Qualifications Required:

- MD, PhD or other higher post graduate qualifications/accreditation in oncology, nuclear medicine or radiology

Required Experience:

- Minimum of 5 years' clinical development experience; proven therapeutic competence.
- Clinical (patient care & research) experience beyond that obtained in the terminal degree program
- Demonstrated record of scientific/medical publications
- Track record of successful drug development/regulatory interactions; biotech experience an advantage
- Thorough understanding of ICH GCP and pharmaceutical ethical codes
- Able to travel internationally

We set about **mapping out similar diagnostics & imaging businesses** as well as reaching out to our network in the Pharma, Medical device and academic sectors. Finally, we researched articles that had been published on similar technology and reached out to the relevant primary contributors.

During the initial search we realised that to fulfil the requirement the candidates were going to need **10+ years' experience** to meet all the criteria. To ensure that we were successful we met with the chief medical officer and developed a first stage technical interview and desired responses that we conducted in house.

Whilst we were conducting our search the other agency produced two possible candidates resulting in BED asking us to put forward one candidate that we felt was the primary option.

As part of our solution **we developed an initial technical screening interview alongside the CMO**. With three high level candidates already through the technical screening process we selected one to put forward against the two from the other agency. The **decision was based on the candidate's performance at the technical screening and their suitability from a team and business fit**.

After a 3-stage process (2 of which were conducted in-house), our candidate was successfully selected and joined the business shortly afterwards. Spending time upon our initial engagement to qualify exactly what BED wanted and then developing a clean and robust process enabled us to find the right candidate and to **fulfil BED's role 40% quicker than their usual time to hire** as well as cutting down on the time BED's internal resource spent on the process.

BLUE EARTH
DIAGNOSTICS
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