

NEW CEO TO SPEARHEAD BIOTEC'S GROWTH



Biotec Services International Ltd would like to introduce its new Chief Executive Officer (CEO), Keren Winmill, who has been appointed to spearhead the company's next stage of growth.

While Keren, who won the Science and Technology category of Welsh Woman of the Year in 2003, takes the position of CEO, founder, Marc Weinzwieg, will remain a non-executive director and major shareholder and will continue his role as head of business development in Israel.

Keren is a highly experienced pharmaceutical and general management professional with particular technical expertise in clinical supply management and a background in both the research-based pharmaceutical industry and the pharmaceutical services sector. She is also internationally recognised as an expert in clinical supplies legislation and practise.

Over the past 12 years Biotec has grown from a small fundamentally Welsh-based organisation, to become a key player in the global pharmaceutical market, generating an annual turnover of more than £3 million.

Now growing at a substantial rate, founder Marc Weinzwieg identified the need for an individual who is capable of maintaining the

momentum and managing the next stage of growth. Marc has made the decision to step aside into a more consultative role on the board and oversee the processes, while Keren will be the driving force behind Biotec's continued success and expansion.

Keren Winmill says, "I am thrilled to take on the role of CEO at Biotec Services International Ltd.

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The company has experienced a great deal of growth and success over the past 12 years, which has accelerated in the last 18 months and

is in a very exciting position internationally. Winning the MediWales Export Achievement Award at the end of 2008 and now The Queen's Award for Enterprise in International Trade have been particular honours and both highlight the phenomenal achievements of Marc and his team in recent years".

"My plan over the next five years is to continue to grow Biotec's client base internationally in order help take the company to its target of £10million turnover per annum and to position Biotec as a leading services organisation Worldwide".

RAPID GROWTH LEADS BIOTEC TO EMPLOY FINANCIAL CONTROLLER

Biotec has appointed Ravi Nalliah in the newly created position of Financial Controller, following a very successful 2008.

Ravi joins Biotec from Broomfield & Alexander, where he held the position of Corporate Finance Manager. Ravi's role included formulating strategic business plans and financial projections for clients, assisting with credit control, cash flow management, budgeting and restructuring and reviewing the management of accounts as well as managing the corporate finance department.

Biotec also welcomes



Ed Lewis to the team as a Senior Project Manager. Ed has many years' experience in the project management of high value, complex clinical trials and commercial contract manufacturing projects for businesses in Europe, US and Asia.

BIOTEC SCOOPS PRESTIGIOUS QUEENS AWARD AND TAKES A TRIP TO THE PALACE



Biotec Services International has been awarded the UK's most prestigious award for business performance at The Queen's Awards for Enterprise by receiving the accolade for International Trade.

The Queen's Awards for Enterprise are recognised as the UK's most prestigious awards for business performance. They recognise and reward outstanding achievement by UK companies in the areas of international trade, innovation and sustainable development. The awards are made each year by Her Majesty The Queen, on the advice of the Prime Minister, who is assisted by an Advisory Committee that includes representatives of Government, industry and commerce,

and the trade unions.

Biotec's CEO, Keren Winmill said, "We were delighted to receive this incredibly prestigious award for international trade from the Queens Awards for Enterprise. Biotec has invested a great deal of time and money targeting pharmaceutical companies overseas that had an outsourcing requirement for clinical trial supply services or specialist storage of temperature sensitive pharmaceutical products".

Following the receipt of the Queens Award in April, the equivalent to a company knighthood, Marc Weinzweig, founder of Biotec and head of business development in Israel and Jeremy Martin, Planning Manager at Biotec,

attended a special evening reception for Queens Award 2009 winners at Buckingham Palace, hosted by Her Majesty, The Queen and other members of the Royal Family.

Then on Friday 24 July, Biotec organised an official Queen's Award presentation ceremony, in which the company was presented with its official award by the Lord Lieutenant of Mid Glamorgan, Mrs Kate Thomas. The event was attended by all Biotec staff, as well as the Deputy Mayor of Bridgend, Councillor Colin Teesdale and the Lady Mayoress, Gloria Teesdale, members of International Business Wales and the representatives from the Welsh Assembly Government.

BIOTEC SECURES BUSINESS IN JAPANESE MARKET

Biotec is making moves to secure clients in one of the largest and lucrative pharmaceutical markets in the World, following a very successful trip to Japan.

Biotec has joined forces with Osaka based CoreMed Corporation to help promote the services that Biotec can offer potential clients in the Japanese pharmaceutical industry. CoreMed will act as a representative for the firm, who recently experienced massive growth following steps into the US market.

Business Development Director, Fiona Withey commented "Japan has a thriving pharmaceutical market and we are aware that there are a number of companies that are looking for a company in the UK to act as a gateway for them into Europe. At Biotec, we are already supporting more than 80 clinical trials and we have the capacity and facilities to store products over a wide range of temperatures, even as low as -196°C".

"CoreMed will act as a representative for Biotec in Japan to help find companies that require the services we offer and in return we will help CoreMed locate non-Japanese pharmaceutical companies who require contract regulatory and strategic development services. We are delighted with the agreement and are confident that it will benefit both businesses".

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COLD CHAIN STORAGE DEMANDS FOR TISSUE ENGINEERED PRODUCTS RESULTS IN GROWING BUSINESS FOR BIOTEC

Biotec has been experiencing rapid growth in its cold chain storage and distribution service, particularly for biological products and has expanded its low temperature storage facilities with the addition of new -196°C cryostores, increasing its storage capacity at this temperature by 300%.

Biotec started offering ultra low temperature (ULT) storage facilities of below -70°C for clinical trial products in 2000 and since then has experienced significant growth in revenue from companies demanding the service for their clinical trials. Seven years later, 10% of the annual revenue generated by Biotec is coming from clients requiring a storage facility of below -70°C.

Growth has been fuelled by clients in particular from the US and Israel conducting clinical trials with tissue engineered products requiring Biotec's Qualified Person, packaging and labelling, storage and distribution expertise within this area.

QP (Qualified Person) and Founder of Biotec, Marc Weinzwieg is a leading industry expert in the handling of cold chain products and has given a number of presentations at key global pharmaceutical conferences on the roles and responsibilities of the QP when handling cold chain products.

Biotec started offering the facility to clients in 2000 and since then has seen a year on year rise in the need to

store cold chain products.

Operations Director, Rachel Griffiths said, "We offer clients -20°C, -80°C and -196°C storage facilities for their cold chain products and are currently running more than 80 clinical trials for clients across the globe. Since we moved into our new purpose built facilities last year we have great deal more space and flexibility for the storage of temperature sensitive products."

"Biotec's operational personnel are specifically trained to handle cold chain products and between myself, Planning Manager, Jeremy Martin and QP, Marc Weinzwieg, we have many years' experience in handling Cold Chain products. Not to mention the new CEO, Keren Winmill who has extensive

experience in the clinical trials industry and will lead the company during its next phase of growth".

Biotec also employs a team of six experienced qualified QPs to ensure that all the products handled are verified, checked and validated before distribution.



BIOTEC INTRODUCES INNOVATIVE NEW LABELLING SYSTEM

Biotec has introduced a new labelling system to its clinical trials process to help increase flexibility, increase efficiency and reduce costs to clients. The new Prism Medica Labelling Software, which is compliant with EU and US regulatory requirements, has a flexible label design to allow the input of variable data per production run and access to stored information for label reprints.

The new labelling system will be fully operational from July 2009 and will allow Biotec to design and print a large variety of labels in-house, including tear-off & wrap-around labels, without the need to outsource.

Benefits include:

- Variable data information printing - This will mean that variable information can be entered per production run such as batch number or expiry date, resulting in reduced wastage.

- Variable data can be printed onto multi-language booklet labels
- Automatic label printing from electronic randomisation codes

An automated system will save time and reduce the risk of errors.

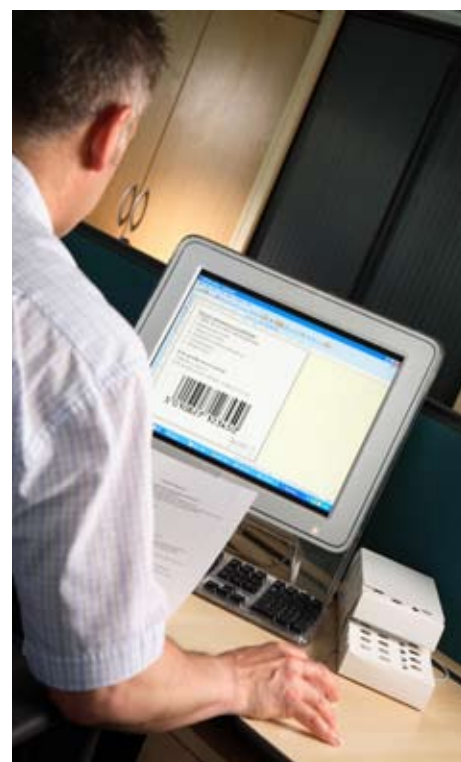
- Ability to prepare randomisation codes in-house

This will provide Biotec with an additional service provision to support the clinical trial set-up.

- Ability to provide decoding solutions
- Decoding mailers can be provided to the study sites and other relevant parties to be kept for unblinding purposes.

- Easy access to archived information

The software will store all information regarding label production for the duration of each clinical trial and can be easily accessed and retrieved for audit purposes.



All about *me*. Meet the Quality Team



Tristram Evans
Quality Assurance Manager

1. What do you enjoy most about your job?

Every day is different. Working with clinical trials and IMPs the challenges we face are often unique. A thorough understanding of the regulations and customer requirements is essential in ensuring a satisfactory outcome for all parties in resolving and over coming these challenges.

2. Do you have any hobbies, if so what are they – anything interesting?

I really enjoy going snowboarding in the winter and normally manage to go twice a year. During the rest of the year I enjoy mountain biking as Wales has some of the best mountain bike terrain around so its an easier hobby to have than snowboarding - artificial ski slopes in Wales leave a lot to be desired compared to the real thing!!

3. Do you have any burning ambitions, if so what are they?

I'd like to try Heli-Snowboarding preferably in N America, the snow off-piste would be superb.



Perry Francis
Systems Engineer

1. What do you enjoy most about your job?

Every day is a challenge and every day is different. The team that has been assembled at Biotec, although extremely knowledgeable are easy to work with and are always willing to assist. This ensures that good team spirit and team ethic are the norm.

2. Do you have any hobbies, if so what are they – anything interesting?

I am a keen Rugby enthusiast; I follow Wales, the Ospreys and Celtic Crusaders RLFC loyally, so I am no stranger to disappointment!

3. What is your favourite film and why?

My favourite film is The Godfather, the acting is superb and the story line seems to capture that moment in time completely. An epic.



Helen Thomas
QC Inspector

1. What does your role in the Quality Assurance team entail?

QC Inspection of incoming, in-process and finished materials.

2. What do you enjoy most about your job?

Gaining further knowledge of new working procedures.

3. If you could go anywhere in the World, where would you go and why?

Japan – I've always been fascinated with the history and culture.



Brian Williams
QP

1. If you could go anywhere in the World, where would you go and why?

At the moment, the Bay of Naples, Vesuvius and Pompeii because it's a time capsule of Roman life.

2. Do you have any hobbies, if so what are they – anything interesting?

Model railways, classic cars and collecting wartime memorabilia.

3. What is your favourite film and why?

Battle of Britain. Wonderful air combat footage.

Latest News

Biotec Services International has teamed up with Biotech PharmaFlow to offer an innovative and unique industry solution for clinical trial supply companies.

The offering will provide sponsor companies with complete support across the clinical trial supply spectrum. Services will be tailored to individual sponsor company requirements, ranging from management of once-off shipments to complete management of the supply programme for one or more clinical trials, to include:

- Material sourcing (including comparators)
 - Storage, packaging and labelling (to cGMP).
 - Inventory management.
 - EU Qualified Person release (where necessary).
 - Supply, Quality/Technical and Service Level Agreements.
 - Supply planning and tracking, from raw/starting materials to IMP/FP.
 - Clinical trial logistics, contractor-to-contractor and study sites.
 - Customs, duty liability, declared values and terms of trade.
 - Handling of couriers and freight forwarders (to cGDP).
- Other services available are advice and guidance on supply chain regulatory compliance aspects, CMC and quality issues, preparation for later stage clinical trials up to phase IV and full scale commercial supply, lean supply and six sigma approaches.

2009 diary – Members of the team will be attending the following conferences. If you would like to arrange to meet up with us please do not hesitate to contact us.

13th – 15th October 2009

The International Contract Service Expo (ICSE)
Feria de Madrid, Spain

Visit us in Hall 8 in the clinical trial zone,
at **Booth 8CT22**

22nd October 2009

BioTech 2009 Central Hall, Westminster

9th – 11th November 2009

2009 AAPS Annual Meeting and Exposition
Los Angeles Convention Center,
Los Angeles, CA, USA

Visit us at **Booth 750**

Christmas close down dates

Biotec will close at 1pm on Thursday 24th December and re-open at 9am on Monday 4th January 2010. The emergency on-call service will operate during this period.

Please ensure that all requests for packaging and shipments are received by Biotec by Wednesday 16th December. The last date for shipments will be Tuesday 22nd December.

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