

Israel - A Country Focus

Israel, sitting at the far eastern shore of the Mediterranean, is a fascinating country with growing technological, pharmaceutical and biotech industries. It has nine state-subsidised public universities, including the Hebrew University of Jerusalem and Tel Aviv University, which are ranked among the world's top 100 universities by the *Times Higher Education* magazine, and there are more than 3000 high-tech companies and start-ups, the highest concentration of hi-tech companies in the world (apart from Silicon Valley).

It is a country which encourages science, technology and education as an absolute tenet of the culture, with more museums per capita than any other country and the world's second largest output of new books per citizen. Life expectancy is considerably higher than the global average, at 82.2 years for women and 78.5 years for men.

Israel has been at the forefront of some of the major technological advances in recent years, with telecommunication taking a major part. Development of the very first cellphone was partially done in Israel by Motorola (which has its largest development centre in Israel), and voicemail technology was also developed in Israel. Much of the Windows NT operating system was created by Microsoft-Israel, and the Pentium MMX chip technology was designed in Israel by Intel. The first

anti-virus software was developed in Israel in 1979. The firewall was invented by Check Point, an Israeli company now known the world over for its information security products. Over 90% of Israeli homes use solar energy for hot water, the highest per capita in the world. Israel is one of few countries in the world to have a space programme. It can design, build, launch and operate its own satellites.

Lying within the Middle East, it is culturally unique, with a diverse population of multiple religions and faiths. Israel has the third-highest rate of entrepreneurship – and the highest rate among women and among people over 55 – in the world. Apart from the US and Canada, Israel has the largest number of NASDAQ listed companies. Israel has a higher percentage of twins per 1000 births than anywhere else in the world. More twins are born in Israel than in Britain, France and Germany. This is principally due to the government's fully-funded fertility treatments.

There is extensive farming, ensuring that the country is largely self-sufficient in food production, apart from grains and beef. The ongoing shortage of water spurred innovation in water conservation techniques, and a substantial agricultural modernisation, drip irrigation, was invented in Israel. This is used to farm hugely productive palm trees. An average palm produces 17kg



of dates a year. Israeli palm trees produce over ten times as much – an average 182kg a year! Its famous Jaffa oranges were transported to the port of Jaffa on the first railway in the Middle East, officially opened in September 1892.

Israel is the only country in the world to have free trade agreements with the US, Mexico and Canada as well as the European Union and the European Free Trade Association, at the same time. In 2010, it joined the OECD and was ranked 17th among the world's most economically developed nations, and it has been ranked as the world's most durable economy in the face of crises. Trade between the EU and Israel is conducted on the basis of an association agreement. The European Union is Israel's biggest trading partner. In 2013 the total volume of bilateral trade (excluding diamonds) came to over €27 billion. In 2013, 32% of Israel's exports (excluding diamonds) went to the EU, and 34% of its imports (excluding diamonds) came from the EU.[1] The relationship with the EU is paramount to ensure continuing economic harmony, whilst ensuring inclusion in sporting events, and because the Israel Broadcasting Authority (IBA) is a member organisation of the European Broadcasting Union, they are eligible to enter the Eurovision Song Contest which they have won three times, most recently in 1998 with Dana International.

Israel is at the forefront of the clinical trials arena, with Israeli scientists working to pioneer new drugs and treatments, and every step of drug manufacturing, from development to clinical trials to the release of the drug being performed in Israel, by pharma companies headquartered both in and out of Israel. Research and manufacture of drugs occurs for such diverse conditions as diabetic macular oedema and age-related macular degeneration, kidney disease, neurological disorders, auto-immune disease, advanced colon cancer, multiple sclerosis, epilepsy, septic shock – the list goes on.

There are a number of countrywide associations including Pharma Israel which encourages interaction between Israeli subsidiaries of multinational companies, leaders in medical research and development. Pharma Israel aspires to create an environment that attracts multinational pharmaceutical companies to invest in the research and development of innovative medicines in Israel, while ensuring the safety of medications and their accessibility to the public.

Well over 5000 clinical trials within the country have taken place to date. With such a diverse population, it is ideally suited to provide data on varying genotypes and ethnicities.

Clinical supplies sent into Israel since Oct 1, 2013 have required medication to go through a QP (qualified person) release process, in a depot location. Shipments are stored under quarantine at the required temperature until after successful QP release from which they can be delivered to

the site(s). This process of QP release can take 24 hours or more and the main aim is to confirm that the drugs arrive at the depot under correct temperature and other required conditions.

This requires the importer of record on the invoice to be a depot, which has received a special permit from the MOH to import investigational medication. CROs can no longer act as IOR for any shipments. Delivery direct to site(s) is no longer possible. For all QP releases, proof of qualified packaging or temperature data is required. This may be handled most simply by including a temperature monitor with every shipment, which can be downloaded at the depot.

Original paperwork is no longer needed for most clearances. Exceptions include shipments with a certificate of origin from the US / Canada / Mexico, which must be original. Also shipments sent with an EUR1 require the original form to be attached to the airline paperwork. (An EUR1 is actually an EUR1 Movement Certificate and is used to support claims for preferential (usually zero) rates of duty in the country of importation.) For shipments from the EU to Israel, it is recommended that the EUR1 form should not indicate the country of origin but state "made in EU" to avoid customs problems if there is any chance of the flight to Tel Aviv arriving from a country different from the origin.

If the value of contents is less than 6000 Euros, then a declaration akin to a certificate of origin can be part of the invoice, in which case the invoice must be original. All imported drugs for human use in clinical trials are exempt from VAT in Israel. Customs overtime during weekdays (shippers should remember the weekend runs from Friday afternoon through Saturday) is possible if pre-arranged with customs by 15:00 Friday, and pre-clearance is done. Extra charges may apply. Shipments with a value over USD200 or 20 kg in weight must go through formal clearance procedure.

In conclusion, Israel is a great country to perform clinical trials in, due to its diverse population, consistent customs handling and highly-skilled clinical professionals!



Sue Lee has worked for World Courier for 25 years. During this time she has experienced a variety of customer service and operational functions, including the setting up of numerous, multi national, clinical sites for the transportation of biological samples in her capacity as Head of the Major Clinical Trial Unit. Sue has orchestrated the shipping thousands of shipments with very specific temperature requirements to a host of challenging locations, and each presenting their own obstacles and dilemmas. More recently in her role as Regional Quality Manager, Sue has been auditing and developing procedures and systems for regulatory compliance, package and vehicle testing, as well as temperature control and mapping.

Currently, Sue's role includes delivering pertinent, technical information and updates on latest industry developments via technical presentations, articles and white papers, workshops, association and discussion group involvement and direct links with other industry professionals. This also includes direct involvement delivering and maintaining World Courier's online presence.

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