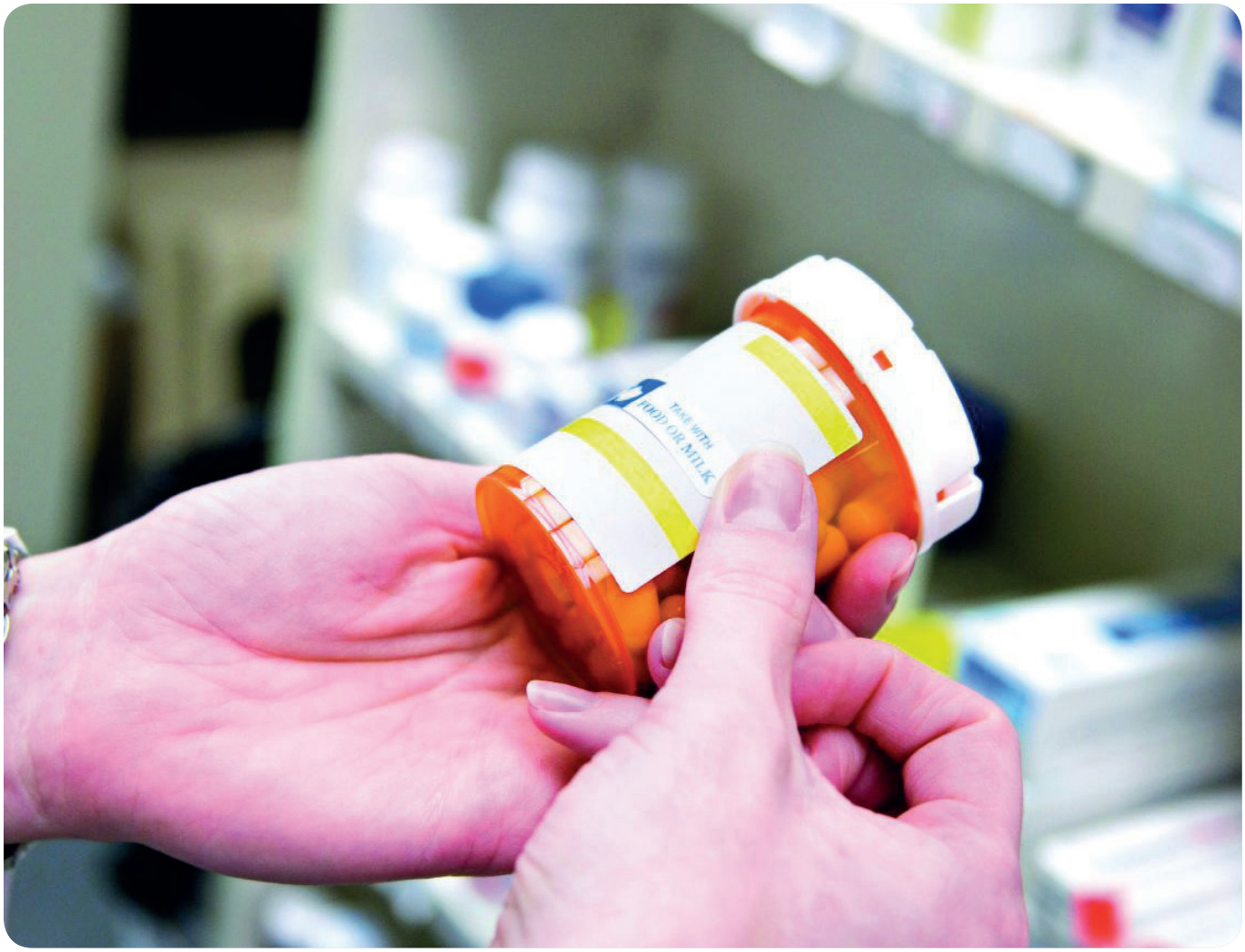
Australia – An Attractive Location for Clinical Studies

This issue we're going to look at Australia, which is a member of the United Nations, G20, Commonwealth of Nations, ANZUS, Organisation for Economic Co-operation and Development (OECD), World Trade Organization, Asia-Pacific Economic Cooperation, and the Pacific Islands Forum, and is a very attractive location for clinical studies.

It is the world's sixth-largest country by total area, with a population of 23.6 million people, and the fifth-highest per capita income globally according to the IMF 2013 figures. We should not underestimate how vast this country is. Perth is closer to Singapore and Jakarta than to Canberra. Australia has the fourth-highest life expectancy in the world after Iceland, Japan and Hong Kong, although as might be expected, due to the hole in the ozone layer it has the highest rates of skin cancer in the world, and that's before you encounter all the hazardous creatures like box jellyfish, platypus, spiders and snakes (which I am reliably informed are mostly avoidable).

The population is very diverse, which can provide companies with extensive data from different ethnicities and genotypes. Typical Western diseases including cardiovascular disease and diabetes are prevalent, together with dementia and Alzheimer's. It has for years been a great area for both pharmaceutical R & D and for clinical trials, with 4487 trials run to date. Almost half of trials are concentrated in Victoria, which is the most densely populated state.

Australia operates a universal healthcare system, with one doctor per 322 people, and 8.5% of GDP spent on healthcare. Australia has a mutual recognition agreement in place with the European Medicines Agency for pharmaceutical manufacture and inspection. The Australia Therapeutic Goods Administration (TGA) is part of PICS – the Pharmaceutical Inspection Cooperation Scheme, so dealing with Australia should be as simple as with the EU or North America, reducing numbers of audits and site visit requirements and relieving some of the paperwork pressures on exported materials.



There are excellent airline services, with plenty of flights particularly into Melbourne and Sydney, although international clearance can be made at Adelaide, Perth, Sydney, Brisbane and Melbourne, with pre-clearance setup options available, allowing documents to be sent in advance by fax or email. Clearance normally takes just a couple of hours, but in the event of a delay then refrigerant can be added/changed

a. when under Customs control
b. when under airline control
c. when being domestically transhipped.

Importing Clinical Trial Drug
All drugs require a customs invoice which must be dated and include the following information:

- Name of product
- If the product contains no ingredients of animal, plant or microbial origin, the following statement is required. "100% synthetic contains no ingredients of animal, plant or microbial origin"
- No. of vials
- Value (noting that NCV – No Commercial Value – is NOT accepted)
- House airwaybill number
- Shipper's signature
- Incoterms are required if the FOB value is AUD1000 and above
- Customs Harmonised Tariff code

Clinical trial drugs also require an import licence called a CTN (Clinical Trial Notification). Usually this is obtained by the sponsor of the trial. Only a copy is required for clearance, not the original. The investigator site must be listed on the CTN import paperwork during the CTN application.

There is a special exception to the above from the TGA. A shipment may be imported into Australia while the CTN is "pending approval". The conditions are that the drug must not be distributed or supplied prior to the CTN approval, or must be destroyed if approval is not obtained within 12 months. A declaration from the importer of record is required to confirm understanding that the drug will be stored and not distributed/supplied. Biological-based drug requires an AQIS import permit from the Australia Quarantine Inspection Service, and if the drug contains any controlled substance(s), a single-use import permit from TGA Dept Health & Ageing may be required. Original permits must be available at the time of import.

If the commodity is subject to quarantine clearance, then clearance must be obtained during the normal business hours of the Quarantine Department. If it is scheduled to arrive over a weekend, then pre-clearance must be arranged by 1630 Friday, and weekend clearance can be arranged.

For North American and European companies in particular, Australia is a very safe option. No language barriers, mature investigational sites mostly based within Victoria State, lots of local infrastructure in place, with well-established CROs, SMOs and depots which can also supply other parts of Australasia – in fact the only disadvantage might be the time difference, although Australians recognise that issue and are very flexible, in my experience, at taking late-night and early-morning calls. It's an excellent place to do business, and a great source of well-researched and compliant data.

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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