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H2O Clinical, LLC



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推薦單位 Recommended by :

駐美國台北經濟文化代表處/高碩泰大使

Taipei Economic and Cultural Representative Office in the United
States/Ambassador Stanley Kao

營業項目 Business Items :

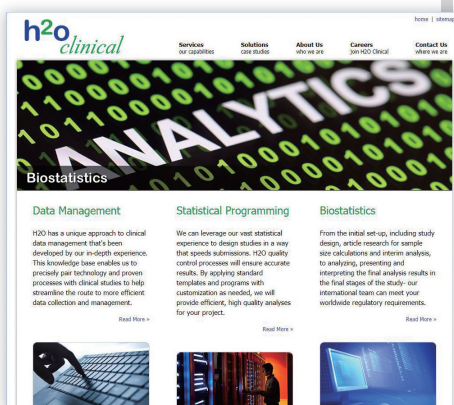
新藥研發報告書遞交、研究報告書、資料庫、統計分析結果、醫學
報告發表、病歷資料收集系統設計。

NDA Submission, Study Report, Database, Analysis Results,
Publications, Case Report Form Design.

產品名稱 Main Products :

治療腦瘤疾病、抗生素藥物、減緩阿茲海默病症藥物、抗憂鬱症藥
物、麻醉用藥、心臟核磁共振顯影劑、治療慢性腎臟病所造成的貧
血、關節炎用藥等

Gliadel, Zithromax, Aricept, Zoloff, Suprane, AdreView, Roxadustat,
HUMIRA...etc.



公司網頁 Website



各類獎座、獎狀 Trophy and certificate merit



公司大門全景 Company entrance overview



研發部門主管聚餐 Banquet of R.D. managers

H2O Clinical, LLC.是專業分工的生技服務業，運用專業的醫療知識、統計分析方法以及電腦程式編寫等專業技能，幫助各大藥廠完成各項研發計畫並推動新藥核准上市，以提升各式疾病患者的治癒機率以及生活品質。

白手起家 立足美國尖端醫藥科技

董事長白越珠統計博士與其先生白偉博醫學博士，兩人憑藉著統計及醫學專業領域的結合，致力貢獻於醫藥研發，夫妻倆胼手胝足，於2011年創辦H2O公司；2015年又於台灣成立H2O分公司，將H2O公司擴展為多元化服務以及全球化的醫藥研發中心。

H2O公司經手過200多個研究計畫，包括48個新藥申請專案，其中經過美國FDA核准上市之藥物高達45個，如此優異的成績奠定了公司發展的基礎。

2013-2016年連續4年榮獲美國奇異醫療研發集團頒發卓越研究獎，2015年榮獲甲骨文公司頒發的新星之獎，更於今(2017)年獲得美國梅林塔抗生素研發藥廠以媒體公開表揚公司研究成果之殊榮，以及美國珐博進藥廠於2017年8月頒發新藥研發成就貢獻獎。



定期員工訓練 Regular training of employees

滾石不生苔 公司之成長、併購、擴張

H2O公司從草創時期的10位員工，擴增至今已有一百六十多位員工；由2011年營業額\$350,000美元至2016年營業額\$20,300,000美元的巨幅成長，正足以說明其事業的蓬勃發展、蒸蒸日上，極具前景。

惟H2O公司沒有因此停歇腳步，2016年1月與TSCP投資顧問公司合作，大幅擴展公司規模，也因此另行設立業務開發部門，期許利用積極尋找合作機會的方式再創H2O公司另一波高峰；2016年6月併購PharmaStart生物科技公司，使公司擴大為全方位的生技研發產業。

管理哲學 精益求精

H2O公司設立了完善的員工訓練制度，定期邀請專家設立各類疾病講座以增進員工醫療常識，並定期提供專業證照訓練課程提升員工的專業技能。

公司著重和諧管理，謀求最高效率以達到共同富裕，全體員工就如同大家庭，氣氛融洽



部門會議 Departmental meeting

和諧，員工間具有強大的向心力。此外，在員工福利措施部份，提供年度員工旅遊、401K退休基金貼補、醫療健康保險、工作表現優異獎金、年度加薪制度以及長短期工作傷殘補助等等，都使員工及其家眷受惠，使員工能無後顧之憂的為公司服務。

成功-你需要的是耐心：一分耕耘、一分收穫

要立足於美國尖端醫藥科技，憑藉的不是運氣，而是要不斷的努力及新知識的吸收，在海外創業，更需要對當地醫療法令有深刻的了解。影響白董事長最深刻的一句話就是：「在成功的道路上，永遠不是擁擠的。」唯有肯努力、肯吃苦、肯打拼的人，才能獲得最後甜美的果實。她也常常鼓勵員工「美國遍地是黃金，就看你願不願意彎腰去撿」，努力、努力、再努力就是最好的成功秘訣。

飲水思源，回饋社會

社會公益方面，秉持著「取之於社會，用之於社會」的回饋理念，積極參與社會公益服務並予贊助捐款，為社會盡一份心力。H2O公司活躍於僑社活動，為打入美國主流社會以及推動台美關係而努力，盼能為台灣未來的經濟以及政治外交發展上有所貢獻。

H2O公司相信只要累積無數微小的力量，就能為人類社會帶來正面且巨大的幫助。不論在生物科技研發上、中文教育推廣或是心心念念的台灣，H2O公司將繼續盡所能為人群社會的遠景散播希望的種子。▲



芝加哥分部員工合影 Employees' group photo of Chicago division

Company Focus

H2O Clinical, LLC is a biotechnology service firm that focuses on providing professional services to support major pharmaceutical and biotechnology companies in completing their NDA submissions. It also promotes the approval of new drugs to improve the possibility of curing sufferers of all kinds of diseases, and patient quality of life, with professional medical knowledge, statistical methods, programming, and other professional skills.

Starting from Zero - Company History

Eugenia Henry has a PhD in Biostatistics, and her husband, Earl Webb Henry, is a medical doctor specializing in neurology. They combined their expertise and experience in medicine, and biostatistics to contribute to pharmaceutical development, and founded H2O Clinical in 2011. In 2015, they founded a branch of H2O Clinical in Taipei, Taiwan, and expanded H2O Clinical into a global medical development center that provides diverse services. H2O Clinical has worked on more than 200 clinical studies and submitted 48 NDA submissions. Our most important achievement is that 45 out of 48 NDA submissions have been approved by FDA, thus allowing drugs or devices to be marketed. This outstanding achievement has promoted H2O Clinical to stand at the top of consulting firms in the pharmaceutical industry.

H2O Clinical has received the outstanding CRO award from GE Healthcare 4 years in a row, from 2013 to 2016. In 2015, H2O Clinical also received the Emerging Business of the Year award from Oracle Health Sciences. In 2017, Melinta issued a press release providing very positive feedback on H2O Clinical's performance. In August 2017, FibroGen Pharmaceuticals also gave an Achievement Award to H2O Clinical to encourage and reward H2O Clinical's outstanding work and spirit.

A Rolling Stone Gathers No Moss – H2O's Growth, Acquisition and Expansion

H2O Clinical started with 10 employees in 2011 and has now grown to more than 160 employees. Over the same time, H2O's revenue has grown from US\$350,000 in 2011 to US\$20,300,000 in 2016. These 2 figures prove that H2O Clinical has a great future.

However, we did not stop growing. In January 2016, we collaborated with the TSCP private equity firm to expand the scale of our company, and also set up a business development department, expecting to create another peak for H2O Clinical by actively looking for cooperation opportunities. In June 2016, H2O Clinical acquired PharmaStart to make us a full service CRO.

Management Philosophy – Consistent Improvement to Excellence

H2O Clinical has set up a full set of employee training programs. We regularly invite pharmaceutical industry experts to provide conferences in statistics, medicine, and disease indications. We also provide professional certificate training courses to enhance the professional skills of our employees.

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H²O Clinical – NDA/MAA/PMA Summary List

Therapeutic category	Regulatory submission	Indication	Status
1	Oncology	NDA	Approved
2	Oncology	NDA	Approved
3	Oncology	MAA	Approved
4	Infectious disease / Respiratory	MAA	Approved
5	Infectious disease / Respiratory	MAA	Approved
6	Infectious disease / Respiratory	MAA	Approved
7	Infectious disease	PMA	Approved
8	Infectious disease	MAA	Pending new data
9	Infectious disease	MAA	Approved
10	Infectious disease	MAA	In progress
11	Infectious disease	NDA	In progress
12	Allergy / Immunology	MAA	Approved
13	Infectious disease	MAA	Approved
14	Immunology	NDA (MAA)	Approved
15	Immunology	NDA	Approved
16	Immunology	MAA	Approved
17	Immunology	NDA (MAA)	Approved
18	Immunology	NDA (MAA)	Approved
19	Immunology	MAA	Approved
20	Allergy / Immunology	MAA	Approved
21	Gastrointestinal	NDA	Approved
22	Critical care	MAA	Pending review
23	Pericardial disease system	MAA	Approved
24	CNS/Neurology	NDA	Approved
25	CNS/Neurology	NDA	Approved
26	CNS/Neurology	NDA	In progress
27	CNS/Neurology	MAA	Approved
28	CNS/Neurology	MAA	Approved
29	CNS/Neurology	MAA	Approved
30	CNS/Neurology	MAA	Approved
31	CNS/Neurology	MAA	Approved
32	CNS/Neurology	NDA	Approved

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產品 Product



公司舉辦聖誕晚宴 Christmas feast of company

H2O Clinical's management philosophy focuses on harmony. We ask for the highest efficiency so that we can thrive together. Working at H2O Clinical feels like working in a large family. Our goal is to create a strong bond within the company and create an attractive and high quality work place. Moreover, we provide an extensive benefit program, including health insurance, a 401(k) retirement plan, an annual employee outing, attractive performance-based bonuses, a yearly merit increase, disability subsidy for long-term and short-term employees, and so on. These benefit plans provide an attractive package for our employees and their family members so that they can work for our company without any concern.

Patience and Persistence are the Most Important Components for Success

In order to keep ourselves one of the top medical consulting companies in the U.S., we keep working and absorbing new knowledge instead of relying on luck. To found an enterprise overseas, the thorough understanding of local medical laws is a must. Our favorite English saying is "On the road of success, you can be sure of one thing... there is never a crowd on the extra mile." Only those who put extra effort into everything can get the sweetest results. She often encourages her employees, saying that they can definitely succeed as long as they are willing to work hard, and that working harder and harder is the best tip for success.

Be Grateful, Contribute to Society

H2O Clinical holds to the concept of contribution, "take from society, contribute to

society," actively participating in social charitable services and sponsoring donations in order to do something for society. H2O Clinical is very active in the activities of overseas Taiwanese groups endeavoring for entry into the

mainstream of the United States, and promoting the relationship between Taiwan and the United States. It expects to contribute to the future economic and political democratic development of Taiwan in the future.

H2O Clinical believes that as long as countless small powers are accumulated, they will bring positive and huge help to human society. Therefore, we at H2O Clinical will keep doing our best to spread the seeds of hope for the prospects of human society, no matter the developments of biotechnology, the promotion of Chinese education, or of Taiwan. ▲

綜合評語 Commentary

設立於大華府地區，長期累積的豐厚經驗與快速正確研究成果，創造了獨特性與知名度。積極參與臺灣本土藥廠新藥研發會議，尋求合作機會，協助臺灣本土藥廠走向國際。熱心服務美國當地及僑界活動，以僑社力量積極融入美國主流社會，增加臺灣影響力。

Established in the Greater Washington area, they have accumulated rich experiences and provided rapid and correct results to establish a unique and acclaimed reputation. They actively participate in the new drug R&D conferences with the local pharmaceutical companies in Taiwan to seek cooperation opportunities and assist in the internationalization of local drug companies. Enthusiastically provided services for events in the United States and in the Chinese communities, and integrated the strengths of the overseas Chinese into the mainstream American Society, thereby strengthening the influence of Taiwan.