CONTROLLED RELEASE SOCIETY
Volume 18 • Number 2 • June 2001

NEWSLETTER

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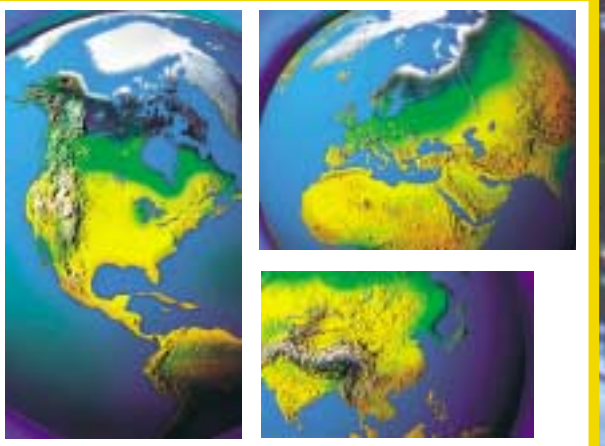

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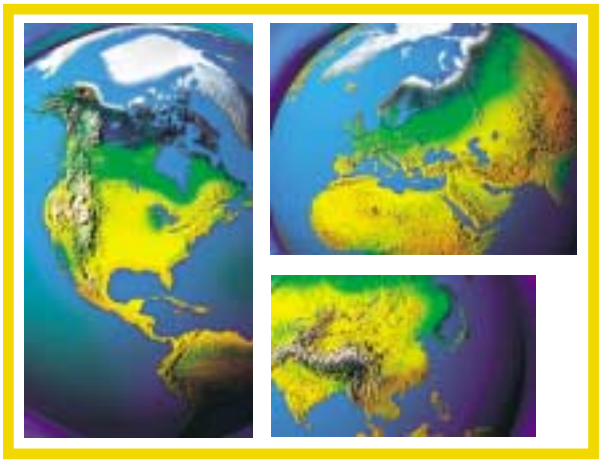
NEWSLETTER

Volume 18 • Number 2 • June 2001

inthisissue



journal of controlled release **highlights**

by David Friend

The latest issue of the *Journal of Controlled Release* (Volume 73) is composed of papers covering a number of topics. Two papers are in the area of oral drug delivery. The first by Steffansen and coworkers, focuses on model prodrugs designed to take advantage of intestinal oligopeptide transporters, namely hPepT1. This di/tripeptide carrier may be able to transport dipeptide prodrugs when the drug would normally exhibit low intestinal permeability. The second paper by Gazzaniga and coworkers describes a more traditional approach to oral drug delivery. Their system, called Chronotopic, is designed to achieve time and/or site specific drug release in the gastrointestinal tract. The dosage form is composed of a drug-containing core surrounded by a hydrophilic swellable polymer. This coating is responsible for the lag phase prior to onset of dissolution and eventual absorption. A pharmacokinetic and gamma scintigraphic study indicated that the tablets delayed drug release and that breakup of the tablets occurred predominantly in the cecum and colon of human volunteers.

Cellular drug targeting remains a challenge to the drug delivery scientist. Amin and Heath have published a paper describing the association of liposomes with cells promoted through LDL receptors. Using cell lines with and without LDL-receptors, they were able to show increased association of liposomes with cells expressing these receptors. However, no increase in LDL-dependent drug potency was observed despite considerable association of the liposomes with the cells. This effect may be due to LDL receptor downregulation.

On the cover –

Balboa Park and the Plaza de Panama is undeniably the cultural heart of San Diego. 28th International Symposium attendees are invited to take in the museums, galleries, and the world-famous San Diego Zoo.

Photo by Brett Shoaf, courtesy of the San Diego Convention & Visitors Bureau.

Editor
David Friend

Managing Editor
Rosealee M. Lee

The Controlled Release Newsletter is the official newsletter of the Controlled Release Society. The newsletter is published three times annually and provides scientific and technical information pertinent to the controlled release community and news about society and chapter activities. Members receive the newsletter via mail. The newsletter may also be viewed online at www.controlledrelease.org.

Editorial contributions should be directed to the Managing Editor, Rosealee Lee (rlee@controlledrelease.org) and are subject to the terms and conditions of the Editorial and Publication Release. Publisher assumes no responsibility for the safety or return of artwork, photographs, or manuscripts.

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from the editor

David Friend

I realized that since becoming editor of the CRS *Newsletter* that I had not published any sort of commentary or statement (profound or otherwise). I have been at this job now for about three years. One might say that I have shown tremendous restraint by withholding any editorial comments. But after three years, I am breaking the silence.

As I indicated at the time of the first issue under my guidance, the transition was an easy one due to Ted Roseman's prior excellent direction. I was also fortunate to keep Melinda Miller as Assistant Editor after Ted retired from his duties. Regardless of the editor, the *Newsletter*'s primary function has been to disseminate information about the Society and its members. Another function has been to present interesting articles wherein authors could expand on their ideas without the often painful scrutiny of peer review. These publications, known collectively as Scientifically Speaking, come at some price to their authors since the *Newsletter* has an impact factor of essentially zero. I fear some poor contributor has had to fight a losing battle at the time of their tenure review when no credit is given for their literary and scientific efforts published in the Newsletter. At the same time, those who take the trouble to read these articles probably appreciate the efforts.

As must be obvious to most, the Society has entered a period of change. The *Newsletter* is changing as well. While the appearance is notably different, the content of the *Newsletter* should continue to evolve as well. For instance, we have yet to publish any independent commentaries from the membership. These comments could address both scientific and management issues facing the Society. An advantage of such commentaries would be that you might hear no more from me since we have space limitations. Anyone with other ideas on how to improve or expand the scope of the *Newsletter* should contact me or the Society office. There is certainly more that we can accomplish with the *Newsletter* and I look forward to working with a larger number of you in the future.

I think back to the time when I agreed to take over from Ted. After three years, why I agreed is still unclear to me although I expect it is rooted in my interest in helping to propagate what I believe to be useful information to the Controlled Release Society. Thinking back further, I wonder why I joined the Controlled Release Society at all. To that question I have a clearer answer: I went to work for Jorge Heller. It is to Jorge I owe a deep debt of gratitude for helping me reach a place where I can hopefully make a few contributions to the field of controlled release science and technology.

VIRSOL

Pascal Breton

Founded in recent years by Dr. Nicole Bru, former owner and President of UPSA (a mid-sized French pharmaceutical company that is now a Bristol-Myers Squibb subsidiary), VIRSOL is the only company in the world that undertakes R&D programs to exploit a unique, patented and continually-expanding methylidene malonate-based technological platform. A fully-owned subsidary of HALISOL, a holding company held by Dr. Bru, VIRSOL is headquartered in Paris (France) where it has been structured into a Business Model based on contractual outsourcing at European and North American universities, public research institutes or other private subcontractors. In that manner, VIRSOL has at its disposal an extensive network of competences that is a par with much larger pharmaceutical entities.

Methylidene malonates (MM), a new class of acrylic monomers, and more specifically methylidene malonate 2.1.2 (MM 2.1.2), have served as key structural elements in the preparation of novel polymers (PMM; among them PMM 2.1.2) and amphipatic or hydrophobic block or grafted copolymers. Synthesis and physico-chemical characteristics of such macromolecules are now perfectly controlled and an increasing body of evidence demonstrates their biocompatibility and underlines some specific and attractive properties. From such chemical materials, pharmaceutical technologists are able to design different types of nanoparticles, microparticles, films, gels, etc… which are produced and tested in biopharmaceutical applications.

Presently, with its 20 employees and its approximately 70 external contract researchers, VIRSOL is sponsoring about 20 R&D projects aimed at increasing the value of such MM-based compounds in various applications and sectors where biomaterials can be of great interest. For instance, VIRSOL is involved in the development of wound care, cosmetics and, of course, drug delivery programs. Most of the drugs with which VIRSOL deals are from biotechnologies and involve essentially peptides and derivatives, recombinant proteins or DNA (oligonucleotides or genes) which have previously demonstrated therapeutic or prophylactic potential, but which would require custom formulation for expression of an optimal *in vivo* biological activity. In the framework of such a strategy, the VIRSOL drug delivery R&D portfolio encompasses innovative approaches in non-viral gene therapy and gene vaccines especially in oncology, ophthalmology, cardiovascular and infectious disease applications.

At its current stage of growth, VIRSOL has established a few corporate partnerships to propagate its MM-based technology. Over the coming months, it is expected that additional R&D collaborative research agreements will be finalized between other companies and VIRSOL. For further information, contact Dr. Pascal Breton at p.breton@groupe-halisol.com or visit www.halisol.com (site remodelling in progress). ●

Focus on Consumer and Diversified Products

Harlan Hall

By the time this issue reaches the members we will have completed the 28th Annual Meeting of CRS. I hope that many of you took the opportunity to check out the activities of the Consumer & Diversified Products (C&DP) group at the meeting. Perhaps you were able to join us for the informal group luncheon following the Technology Transfer Forum on Tuesday, June 26, attended one or more of the sessions, or participated in the pre-meeting workshop on Saturday and Sunday. We hope that you found the meeting useful. If you would like to participate more actively in the C&DP Subcommittee in the planning of future meetings and events, simply e-mail me directly (hhall@encap.com) or via the CRS committee roster which is located online at http://www.controlledrelease.org/about/committees.htm. The subcommittee holds monthly phone meetings (one hour maximum) and is always looking for active participants.

One major objective of the C&DP group is to provide a forum for exchange of ideas for individuals and companies not directly involved in the pharmaceutical business. The Forum section of the CRS website at http://www.controlledrelease.org/forums/index.htm has the potential to be a very useful and flexible means of exchanging ideas and comments. There currently are a few "threads" started; however, to date not many members have utilized this feature. The key to having a useful and vital Forum is participation, THIS MEANS YOU! Post your question or idea, or comment on those of others. Check back every week or so to see if anyone has responded. Initially the responses will be slow; until the Forum reaches a critical mass of users, the interaction won't be that great. But as more people join in, the entire process gains momentum and becomes much more useful. It also is a great way to make contact with others. Sometimes a thought needs to be explored and the Forum is too public. In those cases, use the e-mail address of the other user to make direct contact.

Please feel free to contact any of the subcommittee members. A list of members is available on the subcommittee roster which is located online at http://www.controlledrelease.org/about/committees.htm. •

fromthepresident

Richard Guy

Over and Out

The first thing to ask yourself (assuming that you've read this far) is 'why should I read a message from the soon-to-be ex-President?' What might this "lamest of ducks" have to say that could possibly interest a forward-looking member of CRS? These are good questions, and this is definitely the time to look to the incoming leader, Kinam Park, and to his impressive Board of Directors, for their perspective - I hate that 'vision' word - on the future of our Society.

Rather than attempt to second-guess where Kinam et al. plan to take you over the next few years, I'll take this (ok, yes, self-indulgent) opportunity to reflect on my time as a member of CRS's Board of Directors, and to try and communicate to you why, in the end, I am satisfied with the Society which I pass to my successors, and why I am pleased to have observed at first hand the passage of CRS into the 21st Century.

"CRS has been a pioneer international organization, without question."

First and foremost, CRS today is an intellectually and financially healthy organization. Neither of these attributes has anything to do with me, of course. Previous leadership ensured the fiscal well-being of CRS, and only the chronically incompetent or irrevocably corrupt could alter this situation. Equally, we are lucky to be working in an area - the science associated with controlled release of bioactive substances, to quote the by-laws - which attracts smart people, and which extracts from them clever ideas and research which, in turn, attracts more smart people, and so on.

Attending the annual congress at San Diego provides an opportunity to witness the scientific health of CRS. An important feature, too, at least for me, is the accessibility of the science - a characteristic not always identified with meetings of larger and (allegedly) more successful organizations. An immediate challenge facing CRS, therefore, is how to balance the inevitable growth and development of the Society with its intimate nature. Equally, how does one ensure that the expectations of all members are reasonably and equitably met? To give a specific example, it should be noted that the membership includes more representatives from industry than academia - however, university-based researchers present the greater fraction of the science at our symposia. Are the two groups meeting one another's criteria? If not, what can CRS do to ensure that they will in the future?

Another important issue requiring reflection and, ultimately, action is globalization. CRS has been a pioneer international organization, without question, and the establishment of CRS chapters around the world has been immensely successful. Those involved in the initiation of this idea are to be congratulated - there is no question that this programme has spread the 'controlled release' gospel efficiently and effectively. But, in turn, this success creates new problems because now we have a new constituency of scientists hungry for news and information, for resources (of all types), for the opinion leaders to visit, for doctoral and postdoctoral opportunities, and for financial support to organize local meetings and to attend our international symposia.

All of these needs are justifiable, without question, but can CRS respond usefully to each one? Despite our healthy bank balance, the responsible answer is no, but if one replies in the negative, then (it seems to me) one is obliged to give some thought to a constructive alternative. At present, the good news is that the problem has been recognized and that there is a real desire to resolve the situation. I look forward to the creative solutions which will undoubtedly evolve with time.

"I look forward to the creative solutions which will undoubtly evolve with time."

If nothing else, the above discussion serves to highlight the manner in which CRS has become a more complex organization over the last decade or so, and one which presents new puzzles, novel opportunities and (of course) occasional headaches. This sophistication has placed a greater and greater burden upon the volunteer leadership, and membership of the Board of Directors has become a second full-time job.

(continued on page 8)

Innovation, Convergence and Globalization:

What Matters Most to the 21st Century Biotechnology Industry

The most critical challenges facing biotechnology companies over the next 2-3 years are the creation and protection of intellectual property, the effective use of enterprise technology to capture and share knowledge, and the increasing pressures of globalization, convergence and the regulatory environment, according to a recent Andersen survey that captured the insights and expectations of senior executives from across the biotech industry.

Andersen's Pharmaceutical, Biomedical and Health Services practice sought insights on the issues and challenges facing a biotechnology industry that is in a state of accelerated transformation. The survey – conducted by Knowledge Systems & Research, Inc., (KS&R) – asked a cross sample of senior biotech industry executives from North America and Europe to identify the trends and challenges that are driving priority changes in their companies' business strategies.

"The biotech sector is at the forefront of sweeping change in the global healthcare industry, led by the incredible and continuous development of new technologies and innovations, but these changes are coupled with very significant challenges for the future," said Ed Giniat, managing partner of Andersen's Pharmaceutical, Biomedical and Health Services practice, (formerly known as the firm's Healthcare Industry group). "This research identifies the key strategic concerns of biotech firms around the country and the world, and suggests that industry leaders are preparing to embrace even further change as the regulatory environment becomes clearer and as information sciences continue to accelerate the development of genomics-related products."

According to the survey results, the creation and protection of intellectual property is seen as the most critical area, as nearly all the senior executives surveyed identified an urgent need to address issues such as protecting proprietary research, controlling and extending patent protection, preventing patent infringement, and valuing intellectual property for mergers and acquisitions.

Ranking close behind is the need to respond to the growing influence of technology, as executives cited challenges such as building and maintaining a knowledge base, trading and

(continued on page 12)

(President... continued from page 7)

My predecessor, Gary Cleary, in particular, recognized this daunting challenge and set in motion the steps necessary to ensure that the CRS operation runs smoothly while the leadership considers the "big picture" issues. My presidency has shepherded through this initiative and has emerged, more or less intact, with a new administrative structure, new by-laws, an expanded Board of Directors, and new possibilities ready to be tested and developed.

There is no question that CRS needs to be a more professional operation to survive the exigencies of the new Millennium - the competition for the membership dollar, the journal subscription, the exhibitor booth, the 'diamond' sponsor and the symposium registration is too tough today to rely on the fact that "we did fine last year".

The Board has attempted to be proactive and, yes, aggressive over the last few years with the express intention of leaving my successors with the platform from which CRS can move confidently forward. I am extremely grateful to my fellow Board members for their unswerving support in reaching this objective, and to the membership for its patience and understanding in this period of transition: the next installment in the story can only be exciting and fascinating. Hang on tight! ●

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To learn about the full range of technology-driven solutions from the New Dow, take a moment to visit with us at booth numbers 28 and 29 during the June 23-27 Controlled Release Society's 2001 San Diego Symposium!

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The Impact Factor

Editor's Note: The following is a summary of a article entitled 'Impact Factors: Use & Abuse' published by Mayur Amin and Michael Mabe of Elsevier Science. The entire article is available on-line at: http://www.elsevier.com/homepage/about/ita/editors/perspectives1.pdf. *The issue of impact factors is important to those whose career involves publishing of scientific papers.*

The impact factor (IF) is one of three standardized measures created by the Institute of Scientific Information (ISI). The IF is used to measure the way a journal receives citations to its articles over time. Citations to articles published in a given year rise quickly to a peak between two and six years after publication. Citation curves (number of citations against time after publication) are also used as the basis of the remaining two measures known as immediacy index and cited half-life.

What is the Impact Factor and How it is Affected

Simply stated, the impact factor is a measure of the relative size of the citation curve in years 2 and 3. It is calculated by dividing the number of current citations a journal receives to articles published in those same years. The number that results can be viewed as the average number of citations the average article receives per year in the two years after the publication year.

The value of the IF is affected by sociological and statistical factors. Sociological factors include the subject area, the type of journal (letters, full papers, reviews), and the average number of authors per paper. Statistical factors include the size of the journal and the size of the citation measurement window (time over which the measurement is made).

A common feature of IFs is the variation according to subject field. For instance, the mean IF of journals publishing papers in Neuroscience in 1998 was nearly 2.5 while that of Materials Science and Engineering was about 0.6. Normally, fundamental and pure subject areas have higher IFs than specialized or applied ones. Another feature of IFs is the role of multiple authorship. For instance, social sciences average about two authors per paper while papers published in fundamental life sciences generally have over four authors per paper. Since authors tend to cite their own work, there is a correlation between the average number of authors per paper and average impact factor.

There can also be variation in the same subject area. Short or rapid communications will have greater immediacy but a lower cited half-life. Thus, citations of such articles tend to fall within the two-year window of the IF. On the other hand, citations of full papers peak around three years after publication. These papers tend to decline slowly after their peak leading to a larger cited half-life. Additional information on immediacy and cited half-life of short/rapid communications and full-length papers can be found in the full article.

The IF is also affected by the number of articles published per year. If a large number of journals are examined and the mean variation in IF from one year to the next is compared against size of the journal (that is number of articles published annually), smaller journals tend to show greater variation than larger journals.

Expanding the measurement window from two years (the current JCR standard) can remove some of the statistical variations. An example is provided wherein the average two-year and five-year IFs are compared for 200 chemistry journals over time. While the overall trends were the same, the five year impact was more consistent year to year. Thus, a two year IF can be misleading.

Importance of Variability on Impact Factors

The arguments presented by Amin and Mabe suggest that IFs are subject to a number of conditions that do not directly affect the principal use of such a measure, namely an assessment of the publishing in a particular journal. Some care needs to be taken even when comparing journals in the same subject area. It is suggested that journals with IFs differing by less than 25% belong together in the same rank. Should authors be penalized for publishing in journals with IFs less than a certain fixed value? For instance 2.0, when the evidence suggests that for an average sized journal, this value can vary between 1.5 and 2.25 without being significant?

(continued on page 11)

(Impact Factors... continued from page 10)

The Effect of Numerators and Denominators

The calculation of IFs is based on its formulation and can lead to specific calculation effects. Since it is a ratio, clear definitions of items included in the numerator and denominator are required. Published IFs are the ratio between number of citations to all parts of the journal and the number of papers. ISI classifies papers into a number of different types (articles, reviews, proceedings papers, editorials, letters to the editor, news items, etc.). Only those papers classified as articles or reviews and proceedings papers are counted in the denominator whereas citations to all papers are counted in the numerator. (Editors note: it is common practice for journals to publish review articles as this can increase its IF; this explains why many journals like to have at least one review article per issue).

Conclusions

IFs are one of a number of measures describing the impact that a particular journal can have in research literature. The value of the IF is affected by subject area, type and size of a journal and the window of measurement used. Based on statistical factors, IFs can vary from year to year and therefore interpretation of any given journal's place relative to other journals can be clouded. How IFs are calculated and the range of articles published in a journal can have a role in determining a journal's IF (and in some cases can be manipulated, if desired).

The article by Amin and Mabe attempts to describe (in much greater detail than here) appropriate use of IFs and factors that weaken it when used as the primary measure of a given journal. Interested readers are encouraged to read the full article. ●

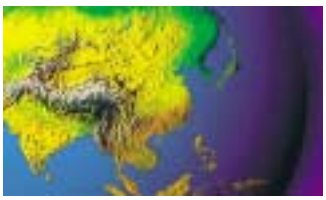
(Innovation... continued from page 8)

acquiring intellectual property, containing costs and increasing profitability, and enabling greater automation in manufacturing.

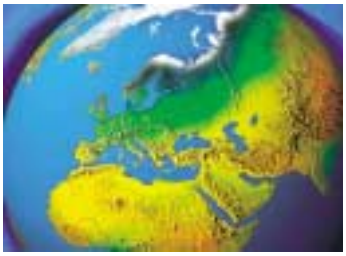
The respondents also identified an imperative need to address the increasing effects of regulation and globalization that have become crucial to the future of the biotech industry. Respondents cited challenges such as the influence of regulatory compliance, the need for a shortened product approval process, and the acceptance of genetics-based controls that may differ across geographical borders. Significantly, most respondents expect a wave of competitive convergence between the biotech and pharmaceutical industries in the near future.

Key findings from the Andersen survey include:

- Intellectual property is a consistently critical impact area. 97 percent of respondents cited protecting proprietary research as a critical challenge, followed by patent infringement (94%), patent control (93%), extending patent protection (90%), and valuing intellectual property for mergers and acquisitions (87%). Protecting proprietary information in databases (74%) and on the Internet (59%) was also cited as major concerns.



- Senior executives recognize the influence of enterprise technology. Across all industry segments, respondents placed significant emphasis on the need to use technology to build and maintain a proprietary knowledge base (87%), trade and acquire intellectual property (78%), contain costs and increase profitability (76%), enhance customer service (70%), add new decision support systems (63%), and automate manufacturing processes (63%).



- The regulatory environment, particularly in North America, is a paramount concern. Respondents identified significant challenges for the biotech industry related to regulatory compliance (89%), the need for a shortened product approval process (89%), and the acceptance of genetic-based products (80%). Regulatory-related cost controls (64%), price controls (76%) and tax compliance (44%) were also listed as specific concerns in this area.

- A wave of globalization and competitive convergence is expected in the near future. 94 percent of respondents expect an increase in joint ventures and cross-licensing deals, but see challenges such as opening new markets (87%), global regulation (85%), the need for greater patent protection (85%), and increased competition (81%). Further, executives expect convergence between pharmaceutical and biotech companies to lead to improved positioning in the global marketplace (72%), and pooled resources for research and development (71%).

Andersen believes that these statistics provide a clear perspective from which to view the future of the biotech industry.

"Clearly, the biotech industry hinges on the use of technology and innovation to effectively develop and protect intellectual property, as well as on the evolution of an increasingly complex global regulatory environment," said Giniat.

"While these results provide an excellent compass for biotech leaders, the real challenges for companies will be to take advantage of consolidation and convergence to drive innovation. As more biotech companies leverage enterprise technology to build and sustain a proprietary knowledge base, contain costs and increase profitability, and improve relationships with customers and suppliers, we'll see an acceleration of new business models and a revolution in the way value is created across the biotech industry landscape." ●

membersrelease

Peer to Peer

Paul M. Stone

For one week a year CRS members from around the globe congregate in a cosmopolitan city to exchange ideas, insights and opportunities. Our Annual Symposium and Conference, along with Local Chapter meetings, provide the formal meeting times within the CRS network. For most of us that leaves 51 weeks a year without an interactive "conversation." In a Society that serves members in more than 50 countries, the geographic expanse can also be daunting. As you know, millions of conversations occur each day on the internet. The internet is currently our best tool to span the globe and provide valuable connections of controlled release researchers on a day-to-day basis. After having several conversations with members and brainstorming sessions with Rosealee Lee, we developed a new online member benefit, the *Peer to Peer Network*. The *Peer to Peer Network* is where CRS members can meet the other 51 weeks a year.

The *Peer to Peer Network* is an online service that offers contact information of members who have declared interest in a specific controlled release area, almost 100 areas and growing. The network is already very popular with researchers showing their willingness to share their ideas and expertise in controlled release. We believe this will be a very powerful tool to communicate within our Society, and it becomes more powerful as each member adds their contributions.

The power of relationships and peer to peer interaction is the number one reason professionals join a society. For CRS members, it could be the journals, annual symposia and conferences, workshops, newsletter, and ever-expanding online resources. CRS bulletin boards also offer members the chance to "talk" online about topics that excite them. If you haven't had a chance, take a moment to log on to www.controlledrelease.org.

Rosealee and I are dedicated to finding ways in which we can enhance your relationship within your Society and within the scientific community. Your feedback is what steers us. Keep up the good work! ●

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September 12-15, 2001
Odense DENMARK
kbrosen@cekfo.sdu.dk
ph: +45-65-916089

Acrylic Bone Cement in the New Millennium:A 40th Anniversary Symposium
September 17-18, 2001
Chancellors : University of Manchester Residential Conference Centre
helen.draper@man.ac.uk
dennis.smith@utoronto.ca

4th Central European Symposium on Pharmaceutical Technology
September 23-25, 2001
Vienna, AUSTRIA
symposium.pharm-tech@univie.ac.at

Drug Delivery 2001: Next Generation Technology
October 1-2, 2001
The Hatton London, UK
kaldrick@smi-online.co.uk
www.smi-online.co.uk
ph: +44-20-7827-6000

Academy of Surgical Research 17th Annual Meeting
October 4-6, 2001
Wyndham San Diego at Emerald Plaza
San Diego, CA, USA
registration@surgicalresearch.org
www.surgicalresearch.org
ph: 763-765-2300

who...what...where...when

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Next issue deadline
August 13, 2001